BEFORE THE VIRGINIA BOARD OF MEDICINE

IN RE: **MICHAEL JOHN BIGG, M.D.**
License Number: **0101-035858**
Case Number: **188642, 198071, 197860, 194361, 200168, 203388**

ORDER OF SUMMARY SUSPENSION

Pursuant to Virginia Code § 54.1-2408.1(A), a quorum of the Board of Medicine ("Board") met by telephone conference call on May 20, 2020, after a good faith effort to convene a regular meeting of the Board had failed. The purpose of the meeting was to receive and act upon information indicating that Michael John Bigg, M.D., may have violated certain laws relating to the practice of medicine and surgery in the Commonwealth of Virginia, as more fully set forth in the attached "Notice of Formal Administrative Hearing and Statement of Allegations," which is attached hereto and incorporated by reference herein.

WHEREUPON, pursuant to its authority under Virginia Code § 54.1-2408.1(A), the Board concludes that a substantial danger to public health or safety warrants this action and ORDERS that the license of Michael John Bigg, M.D., to practice medicine and surgery in the Commonwealth of Virginia is SUSPENDED. It is further ORDERED that a hearing be convened within a reasonable time of the date of entry of this Order to receive and act upon evidence in this matter.

Pursuant to Virginia Code § 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection or copying on request.

FOR THE BOARD

Jennifer L. Deschene

for William L. Harp, M.D.
Executive Director
Virginia Board of Medicine

ENTERED: 5/20/20

STATEMENT OF ALLEGATIONS

The Board alleges that:

1. At all times relevant hereto, Michael John Bigg, M.D., was licensed to practice medicine and surgery in the Commonwealth of Virginia.

2. On or about May 29, 2018, Michael John Bigg, M.D., violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16) and (18) and 18 VAC 85-20-26(C) of the Regulations Governing the Practice of Medicine, Osteopathy, Podiatry and Chiropractic ("Regulations") in the diagnosis and treatment of Patient A, a 54-year-old female. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at Allison Breast Center ("ABC"), the diagnostic imaging center that he owned and operated in Richmond, Virginia, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient A for new, palpable left breast lumps/masses, resulting in his failure to diagnose the patient's left breast cancer. Specifically, when Patient A presented to ABC on this date on referral from her treating OB-GYN for a breast diagnostic work-up:

a. Dr. Bigg failed to order, and radiologic technologists ("RTs") employed by Dr. Bigg failed to produce, sufficient, complete or appropriate mammographic and ultrasound imaging of Patient A's left breast, as follows:

i. Dr. Bigg failed to order a diagnostic mammogram for Patient A, who presented with palpable findings in her left breast. Rather, Dr. Bigg ordered or authorized a screening mammogram, which is appropriate only for an asymptomatic patient.

ii. Mammographic images produced on or about that day by the ABC RT did not include triangle metal markers placed in the areas of concern (location of palpable left breast

lumps/masses) designated by the patient, and thereby failed to appropriately focus attention on the areas of the lump/masses and their correlation on the mammogram.

iii. Despite the fact that Dr. Bigg noted Patient A's concern with palpable lumps/masses, which he confirmed by physical examination, he failed to order and review additional mammographic spot compression views of two orthogonal projections, in these areas of patient concern.

iv. The ABC RT failed to appropriately target Patient A's diagnostic ultrasound images, in that the RT did not label these images to designate the patient's areas of concern.

b. Dr. Bigg misread Patient A's mammographic images. Specifically, Dr. Bigg erred in concluding, in his May 29, 2018 unilateral, left-side screening mammography and ultrasound report ("report") for Patient A, that the patient's mammogram was "[n]egative," as the patient's substandard mammographic images (detailed above), were insufficient to adequately and appropriately visualize the patient's left breast lumps/masses for evaluation and diagnosis. Further, Dr. Bigg noted in this report that his physical examination of Patient A's left breast revealed "two soft adjacent nodules above the nipple on the left side," which he concluded were two adjacent intrammary lymph nodes. As lymph nodes do not commonly reside in this location, Dr. Bigg should not have assumed these palpable findings to be lymph nodes.

c. Dr. Bigg misread Patient A's two ultrasound images. Specifically, these two ultrasound images, obtained by ABC RTs, showed two masses in Patient A's left breast, consistent with the typical appearance of cancer. In his May 29, 2018 report, Dr. Bigg noted his erroneous impression (in the "findings" section of this report), that these images identified "two adjacent intramammary lymph nodes." This impression is on its face discordant with Patient A's two ultrasound images, as said images

do not show key features of intramammary lymph nodes, such as a fatty hilum with vascular flow and a thin, uniform cortex.[1]

d. After Dr. Bigg told Patient A, a registered nurse ("RN") for 32 years, that her May 29, 2018 mammogram and ultrasound images revealed the lumps in her left breast to be lymph nodes that migrated into her breast tissue, the patient reported this diagnosis to her treating OB-GYN, who recommended a second opinion. Approximately six days later, Patient A presented to another practitioner and underwent a breast biopsy and a mammogram, which showed a 1.5 cm irregular mass at 1 o'clock, 4 cm FN (centimeters from the nipple). Three days later, Patient A's breast biopsy pathology report indicated invasive lobular carcinoma.

e. In his undated response to the DHP investigator regarding his care and treatment of Patient A, Dr. Bigg stated that after the ABC RT/ultrasound technologist imaged Patient A's left breast on May 29, 2018, he also performed an ultrasound evaluation. Yet, Dr. Bigg's chart contained a total of two ultrasound images of Patient A's left breast, neither of which identified him as the ultrasonographer.

3. From approximately November 2015 through November 2017, Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the diagnosis and treatment of Patient B, an 81-year-old female (as of March 1, 2017) with bilateral breast implants.[2] Specifically, Dr. Bigg and/or his employees acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient B for a right breast lump/mass, evident on mammographic and/or ultrasound images, resulting in his failure to diagnose the patient's right breast cancer, a follows:

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[1]In his undated "response to the complaint" regarding Patient A, Dr. Bigg stated that his ultrasound evaluation revealed two small, adjacent "structures," with echocharacteristics consistent with intramammary lymph nodes, but again failed to describe such echocharacteristics.

[2]Patient B underwent subglandular breast augmentation with silicone gel implants in or about the 1970s. On or about March 22, 2011, she underwent bilateral total capsulectomies with removal of silicone gel implants and bilateral, submuscular re-augmentation with saline-filled implants.

a. Dr. Bigg misread Patient B's right breast mammographic and ultrasound images, resulting in his failure to diagnose Patient B's right breast cancer. Specifically, Patient B's 2D November 27, 2017 mammogram images obtained by ABC RTs on this date showed a spiculated mass on the right at 10:00, right axillary lymph node involvement, and a right subareolar asymmetry, and the patient's targeted right ultrasound images on this date showed a spiculated mass at 10:00, and an abnormal right axillary lymph node (called 10:00 cm FN), findings which are highly indicative of breast cancer. (ABC RTs failed to image Patient B's right subareolar asymmetry on ultrasound). Yet, in Dr. Bigg's November 27, 2017 screening mammography, bilateral, and ultrasound, bilateral report, purportedly based on his review of the above-referenced images, Dr. Bigg failed to identify and report Patient B's right breast cancerous mass. Rather, Dr. Bigg documented "no specific changes" from Patient B's prior examinations (including November 16, 2015 and November 17, 2016 mammogram images),[3] noted "prominent lymph nodes in the right axilla that have increased in size a little from prior examinations," and in a "Footnote" indicated the presence of "a little progressive adenopathy in the right axilla." Dr. Bigg concluded, "[n]o findings suspicious for malignancy [were] identified," and recommended that Patient B follow up[4] with "[y]early mammography."[5] Had Dr. Bigg accurately diagnosed Patient B, the appropriate follow-up would have been a biopsy referral.

b. Approximately 11 months later (on or about October 29, 2018), Patient B presented to another diagnostic breast center complaining of a new, palpable lump in her upper, outer right breast,

[3]As detailed below, Dr. Bigg indicated in his November 2015 and November 2016 breast mammogram and ultrasound image reports for Patient B the presence of silicone, a finding that Dr. Bigg noted remained unchanged in the patient's November 27, 2017 mammogram and ultrasound images. Yet, silicone in the breast has distinct imaging features: on mammogram, free silicone is hyperdense and on ultrasound, it has a "snowstorm" echotexture with dense shadowing, imaging features not present on any of Patient B's mammographic or ultrasound breast images. Further, no free silicone or calcifications of the fibrous capsule are present on the November 27, 2017 mammogram or ultrasound. Moreover, at the time that the surgeon replaced Patient B's silicone breast implants with saline breast implants (March 2011), neither the surgeon's operative report nor the surgical pathology report for Patient B indicated a silicone implant rupture.

[4]Follow up and management are used interchangeably herein.

[5]In a "footnote," Dr. Bigg indicated, "Clinical correlation is recommended here to consider the possibility of systemic causes of lymphadenopathy," but did not specify such clinical correlation or advise the patient as such.

present for one month, with retracted skin in this area. A bilateral digital diagnostic mammogram performed on this date indicated the following: a 1 cm irregular mass in Patient B's right breast, central to the nipple in the retroareolar region; a 1.8 cm irregular mass in the right breast at 10:00 anterior depth; and a 2.6 cm irregular mass in the right axillary tail. These findings are all highly suggestive of malignancy. A targeted ultrasound performed on this date indicated an oval, hypoechoic mass with an indistinct margin measuring 0.6 x 1.1 x 1.2 cm at 10:00, 5 cm FN, correlating to the mammographic mass at 10:00; and an oval, hypoechoic mass with indistinct margins measuring 1.6 x 1.7 x 1.7 cm at 10:00, 7 cm FN, correlating to the posterior, superior mass seen on the MLO view. The ultrasound images were rated as BI-RADS 5 (addressed below): highly suggestive of malignancy, and requiring biopsy or surgery. In or about November 2018, further diagnostic testing (right breast biopsy, chest CT and skull-to-mid-thigh chest PET CT) indicated invasive ductal carcinoma of the right breast, and numerous bone lesions and pulmonary nodules consistent with metastatic disease.

c. On or about February 1, 2019, a consulting physician reviewed Patient B's November 27, 2017 ABC mammogram and ultrasound in comparison to the patient's November 16, 2015 and November 17, 2016 ABC mammograms. This consulting physician (a radiologist) indicated that the "irregular, high-density mass with spiculated margins at 10:00, middle depth in the right breast" evident in the 2017 mammogram and ultrasound was also present in Patient B's November 2015 and 2016 mammogram images, which originally had been obtained by ABC RTs and reviewed and interpreted by Dr. Bigg. Yet, Dr. Bigg also failed to note this finding in his prior imaging reports. Rather, Dr. Bigg noted in his November 16, 2015 screening mammography, bilateral and ultrasound, bilateral report, a "benign" finding of "[a] little soft-tissue silicone…on the *right* side, unchanged from earlier examinations," and recommended yearly mammography in follow-up; and in his November 17, 2016 screening mammography, bilateral and ultrasound, bilateral report, noted "[b]enign…unchanged" findings "on the

left side...I think represent[ing] a little reactive change associated with an old silicone rupture…[c]ertainly…stable," and recommended yearly mammography in follow-up. (*See Footnote 3*).

4. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the diagnosis and treatment of Patient C, a female patient with a history of smoking and left breast neoplasm (2001) and a family history of breast cancer, and a history of silicone breast implants removed in 2011 with no evidence of leak or rupture, from approximately October 30, 2017 (when the patient was 72 years old) to May 16, 2018. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient C for a new, palpable right breast lump/mass, resulting in his failure to diagnose the patient's right breast cancer. Specifically:

a. On or about October 30, 2017, Patient C presented to Dr. Bigg with a palpable mass in her right breast, at which time Patient C underwent targeted right breast ultrasound. At or about this time, Dr. Bigg misread Patient C's ultrasound images, resulting in his failure to diagnose her right breast cancer. Specifically, these breast ultrasound images indicated an ill-defined, hypoechoic mass on the right at 1:00, and an abnormal right axillary lymph node with cortical thickening; both findings very concerning for a breast cancer with right axillary metastasis, for which appropriate management is biopsy. Yet, Dr. Bigg, in his right breast ultrasound report on or about this date, opined that these images showed a "stable fibroadenoma" (previously noted in Dr. Bigg's November 22, 2016 and February 28, 2017 breast ultrasound reports for Patient C) "[i]ncidental[ly]" noting a bilocular fluid collection in the right axilla, which he opined "could seem to be associated with the glenerohumeral joint and represents a cyst." The images submitted do not show imaging features of a simple fluid collection nor do the images include the glenerohumeral joint; there are no identifiable landmarks on the images to collaborate this impression.

Based on his noted impression, Dr. Bigg instructed the patient to return for her annual screening mammogram in follow-up. A screening mammogram is for asymptomatic patients and not used as a follow-up of imaging findings or patient symptoms.

b. Less than six months later, on or about April 16, 2018, Patient C returned to Dr. Bigg at ABC, complaining of a painful, enlarging mass in her right breast, present for the previous four to six weeks. At this time, Patient C was inappropriately assessed for this complaint. Specifically, ABC RTs performed and Dr. Bigg reviewed, a bilateral screening mammogram (and ultrasound), despite the fact that Patient C presented with a palpable finding, for which the standard of care requires diagnostic mammography.

c. Nonetheless, Patient C's mammographic images on this date showed a hyperdense mass in Patient C's right breast at 12:00. Yet, for a patient with a palpable, enlarging right breast mass, Dr. Bigg reported no mammographic findings in his April 16, 2018 mammography, bilateral and ultrasound, bilateral report ("report," signed on April 17, 2018). Rather, Dr. Bigg noted his impression, that the patient's known fibroadenoma, present "at the site in question for many years," had on the current mammographic examination "clearly enlarged," undergone a "clear contour change," and that its discrete margins were a "little difficult to identify."

d. Dr. Bigg failed to accurately assess and manage cancerous findings evident in Patient C's April 16, 2018 targeted right ultrasound images. Specifically, these ultrasound images correlated an irregular mass in Patient C's right breast, at 12:00, and showed multiple, abnormal, axillary lymph nodes, which were not present in the patient's last imaging on or about October 30, 2017. These findings indicate a classic case of cancer with adenopathy, for which appropriate management is biopsy. Yet Dr. Bigg described his impression, in the findings section of his report, of "an inhomogeneous, predominantly solid, nonshadowing mass that has also increased in size," and failed to note or address the

multiple, abnormal, axillary lymph nodes evident on the current ultrasound images. Based on his misinterpretation of these images, Dr. Bigg concluded that Patient C had "either necrosis within what is most likely a fibroadenoma or hemorrhage." Accordingly, he failed to recommend biopsy, instead recommending ultrasound follow-up, absent a noted a follow-up date or appointment time. Further, Dr. Bigg failed to notify or refer Patient C to her primary care physician regarding further evaluation of the potential hemorrhage.

e. One month later, on or about May 16, 2018, Patient C returned to see Dr. Bigg, with continued complaints of the uncomfortable mass in her right breast, which Dr. Bigg noted at that visit had grown larger and felt hard. Targeted right breast ultrasound images performed on this date, reviewed by Dr. Bigg, showed a spiculated mass at 12:00, and multiple, abnormal right axillary lymph nodes, again evidencing cancer with adenopathy. Yet, Dr. Bigg failed to make this finding. Rather, in his breast ultrasound report, Dr. Bigg described his impression of a "hypoechoic, inhomogeneous mass on the right side," opining that what he previously interpreted "for many years" as a fibroadenoma was currently a "chronic hematoma" on the right. Again, Dr. Bigg failed to note the lymph node finding. Instead of appropriately referring Patient C to a surgeon for biopsy, Dr. Bigg referred the patient for a surgical consult regarding the purported "chronic hematoma."

f. The following day (May 17, 2018), Patient C presented to a surgeon who opined, on reviewing the patient's recent ABC mammogram, that these images visualized enlarged right lymph nodes and right axilla. Upon examination, the surgeon found a large mass occupying most of the upper, outer quadrant of Patient C's right breast. This surgeon ordered right breast and lymph node (right axilla core) biopsies, and recommended removal of this mass, "regardless of" the resultant pathology. On or about May 29, 2018 (approximately 13 days after the patient had last seen Dr. Bigg), based on the pathology results from Patient C's biopsy, this surgeon diagnosed the patient with invasive ductal

carcinoma with micropapillary features. On or about June 25, 2018 (approximately six weeks after the patient had last seen Dr. Bigg), Patient C underwent a right breast modified radical mastectomy,[6] during which the surgeon removed a 9 cm tumor with positive margins, with involvement of 19/19 right axillary lymph nodes. On or about December 4, 2018, Patient C was diagnosed with secondary malignant neoplasm of the lung (or lung masses as distant metastatic cancer).

g. Regarding Patient C's mammographic and ultrasound images taken at ABC between October 2017 and May 2018: Dr. Bigg failed to order and radiologic technologists ("RTs") employed by Dr. Bigg failed to produce sufficient, complete or appropriate mammographic and ultrasound imaging of Patient C's right breast, as follows:

i. Mammographic images obtained by the ABC RTs on or about October 27, 2017 and April 16, 2018 did not include triangle metal markers placed in the areas of concern (location of palpable left breast lumps/masses) designated by the patient, and thereby failed to appropriately focus attention on the areas of the lump/masses and their correlation on the mammogram. Further, Dr. Bigg failed to order and review additional mammographic spot compression views of two orthogonal projections, on either of these dates, in Patient C's area of concern.

ii. The ABC RTs failed to appropriately target Patient C's October 30, 2017, and April 16 and May 16, 2018 diagnostic ultrasound images, in that the RTs did not label these images to designate the patient's area of concern.

5. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the diagnosis and treatment of Patient D, a female patient with a positive family history of breast cancer and a former smoker, between approximately May 16, 2017 (when the

[6]The upper limits of this surgery were limited by the presence of Patient C's defibrillator. On July 10, 2018, Patient C underwent a second surgery coordinated with a cardiologist, who removed the defibrillator in order to finish the dissection (and for purposes of subsequent radiation treatment), and removed the diseased tissue. In or about December 2018, Patient C was diagnosed with secondary malignant neoplasm in her left lung, subsequently treated with radiation therapy.

patient was 60 years old), and May 16, 2018. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient D for a new, palpable, solid left breast lump/mass, resulting in his failure to diagnose the patient's left breast cancer. Specifically:

a. Dr. Bigg failed to order and RTs employed by Dr. Bigg failed to produce sufficient, complete or appropriate mammographic and ultrasound imaging of Patient D's left breast, as follows:

i. On or about May 16, 2017 and again on May 16, 2018, Dr. Bigg failed to order a diagnostic mammogram for Patient D, who presented to ABC on those dates with palpable findings in her left breast. Rather, Dr. Bigg ordered or authorized screening mammograms, which are appropriate only for an asymptomatic patient.

ii. Patient D's May 16, 2017 and May 16, 2018 mammographic images did not include a triangle metal marker placed in the area of concern (location of palpable left breast mass) designated by the patient, and thereby failed to appropriately focus attention on the area of the mass and its correlation on the mammogram.

iii. Based on Patient D's palpable left breast mass, Dr. Bigg failed on May 16, 2017 and May 16, 2018 to order and review additional mammographic spot compression views of two orthogonal projections, in this area of patient concern, and failed on both dates to order a breast ultrasound to target this area of concern.

b. On or about May 16, 2017, Patient D presented to Dr. Bigg with a palpable left breast mass, at which time she underwent mammographic imaging. Dr. Bigg's screening mammography, bilateral report on this date (signed the following day) shows that he misread Patient D's mammographic imaging and failed to appropriately manage the patient. Specifically, Patient D's mammographic images showed a 3.2 cm spiculated mass in her left breast at 6:00, suspicious for cancer. Yet, Dr. Bigg's

impression (erroneously noted in the findings section of this report) was that these images showed "no" masses or suspicious calcifications. Dr. Bigg's failure to note any findings in his May 16, 2017 bilateral screening mammography report for Patient D indicates that there was no mammographic correlate for the finding of clinical concern (left breast lump/mass). Consequently, the appropriate follow-up would be ultrasound evaluation and/or biopsy. Yet, rather than appropriately managing the area of clinical concern with further diagnostic testing, Dr. Bigg reported that the patient's mammogram was "[n]egative" and recommended that the patient return in one year for a routine screening mammogram.

c. On or about May 16, 2018, Patient D again presented to Dr. Bigg with the same palpable mass in her left breast, at which time she underwent mammographic imaging. Dr. Bigg's screening mammography, bilateral report on this date shows that he again misread Patient D's mammographic imaging and failed to appropriately manage the patient, as follows:

i. Patient D's mammographic images showed a 3.4 cm (increased in size from the May 26, 2017 mammogram images) spiculated mass in the patient's left breast, at 6:00, highly indicative of breast cancer. The appropriate management of a palpable, growing, spiculated left breast lump/mass is biopsy.

ii. Yet, Dr. Bigg's impression (erroneously noted in the findings section of this report of Patient D's mammographic images) was that these images identified "[n]o findings suspicious for malignancy." Dr. Bigg's failure to note any findings in his May 16, 2018 report for Patient D indicates that there was no mammographic correlate for the finding of clinical concern (left breast lump/mass). Consequently, the appropriate management would be ultrasound evaluation and/or biopsy in order to visualize and/or diagnose the mass. Yet, rather than appropriately managing the area of clinical concern

with further diagnostic testing, Dr. Bigg erroneously reported that the patient's mammogram was "[n]egative," [7] and recommended that the patient return in one year for a routine screening mammogram.

d. Subsequent to her May 16, 2018 mammogram at ABC, Patient D presented to her treating pulmonologist for a respiratory complaint, at or about which time a chest CT scan showed a small, spiculated mass in the patient's left breast, with a smaller nodule in the left breast; results concerning for breast cancer. Based on these CT scan results, this pulmonologist referred Patient D to a surgeon, who performed an ultrasound-guided breast biopsy on or about November 21, 2018. The surgeon indicated, in his treatment note for Patient D on this date, a palpable left breast lump with skin dimpling and nipple retraction, with the nipple beginning to point downward. Pathology results from Patient D's left breast core biopsy revealed left breast invasive mammary carcinoma with ductal and lobular features, with associated microcalcifications. On February 5, 2019, Patient D underwent a left total skin-sparing mastectomy with sentinel lymph node biopsy, and an immediate reconstruction.

6. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the diagnosis and treatment of Patient E, a female patient with a personal history of right breast neoplasm treated (in approximately 1985) with lumpectomy and radiation therapy, from approximately June 15, 2016 (when the patient was 82 years old) to May 22, 2019. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient E for a new, palpable, solid right breast lump/mass, including, but not limited to, failing to diagnose a right breast cancer evident for three years on three previous mammograms, and issuing multiple confusing, misleading, and/or inconsistent mammogram and ultrasound reports, resulting in his repeated failure to diagnose the patient's right breast cancer. Specifically:

[7] In his May 16, 2018 report, Dr. Bigg simply noted "no skin retraction or edema" and concluded that "No findings suspicious of malignancy are identified."

a. Dr. Bigg failed to order and RTs employed by Dr. Bigg failed to produce sufficient, complete or appropriate mammographic and ultrasound imaging of Patient E's right breast, as follows:

i. On or about May 23, 2017, May 22, 2018, and May 22, 2019, Dr. Bigg failed to order a diagnostic mammogram for Patient E, who presented to ABC on those dates with palpable findings in her right breast. Rather, Dr. Bigg ordered or authorized screening mammograms, which are appropriate only for an asymptomatic patient.

ii. None of Patient E's May 23, 2017, January 9 and May, 2018, and May 22, 2019 mammographic images included a triangle metal marker placed in the area of concern (location of palpable right breast mass) designated by the patient; these images thereby failed to appropriately focus attention on the area of the mass and its correlation on the mammogram

iii. Based on Patient E's palpable right breast mass, Dr. Bigg failed on May 23, 2017, January 9 and May 22, 2018 and May 22, 2019, to order and review additional mammographic spot compression views of two orthogonal projections, in this area of patient concern.

iv. On or about June 15, 2016, May 23, 2017, January 9 and May 22, 2018, and May 22, 2019, ABC RT(s) failed to appropriately target Patient E's diagnostic ultrasound images, in that the RT(s) did not label these images to designate the patient's areas of concern.

b. On or about June 15, 2016, Patient E presented to Dr. Bigg complaining of a painful mass on the underside of her right breast, which Dr. Bigg described in his ultrasound, unilateral right side report on this date (signed the next day) as a "rubbery, slightly mobile, 8mm diameter…soft tissue nodule below the right breast at approximately the 6 o'clock position." Dr. Bigg concluded with "reasonab[le] certain[ty]" that "what we are seeing here is a *reactive lymph node*." He advised Patient E to "refrain from touching it if she can" and to try wearing a sports bra instead of an underwire bra.

c. On or about May 23, 2017, Patient E underwent bilateral screening mammography and ultrasound at ABC. In his screening mammography, bilateral and ultrasound, bilateral report on this date, Dr. Bigg noted the continued presence of a "firm nodule in the inferior mammary fold on the right side…unchanged in appearance," opining (erroneously, in the "findings" section of his report,) that the "nodule" was on this occasion a *small fibroadenoma*, and that since it was no longer painful, he would "just…continue to observe this." Dr. Bigg concluded Patient E's mammogram was "benign" and recommended yearly mammography in follow-up.

d. On or about January 9, 2018, Patient E returned to Dr. Bigg at ABC and underwent bilateral (purportedly) diagnostic mammography and ultrasound, and Dr. Bigg misread Patient E's breast images on this date. Specifically, Dr. Bigg erroneously noted in his diagnostic mammography, bilateral and ultrasound, bilateral report that Patient E presented with a history of a "potential nodule in the *upper-outer quadrant* of the *left* breast and a potential inverted nipple," and that physical examination demonstrated diffuse nodularity of the *left* breast, which ultrasound imaging revealed on this occasion to represent some *glandular tissue*, further indicating that the nipple did not seem to be clinically retracted. Despite the fact that Dr. Bigg's prior findings involved Patient E's right breast, Dr. Bigg noted that mammographically, this imaging of the patient's left breast looked to be unchanged from multiple, prior exams (including Patient E's May 23, 2017 mammogram images), further noted that "no masses" were identified by physical examination or ultrasound, and recommended that the patient return for an annual screening mammogram.

e. On or about May 22, 2018, Patient E underwent an annual screening mammogram and ultrasound at ABC. The right breast mammogram images obtained at this visit do not include/show the area of concern (palpable mass). Yet despite the fact that he failed to correlate Patient E's area of concern with her mammographic imaging, due to the lack of a palpable marker and the lack of

mammogram images targeted to the area of concern, Dr. Bigg concluded in his screening mammography, bilateral and ultrasound, bilateral report on this date (signed the next day), that the patient's mammogram was "[n]egative." Patient E's right breast ultrasound images on this date show that the patient's right breast mass had grown since her 2017 ultrasound, concerning for malignancy. Yet, in this same report, Dr. Bigg noted his impression (erroneously, in the "findings" section) that Patient E's ultrasound images indicated a *stable fibroadenoma* in the inferior aspect of the *right* breast, with no skin retraction. Rather than recommending biopsy as appropriate management of a growing right breast mass, Dr. Bigg recommended annual mammography in follow-up.

f. On or about May 22, 2019, Patient E underwent a screening mammogram and ultrasound at ABC. The right breast mammogram images obtained at this visit do not include/show the area of concern (palpable lump/mass). Yet, despite the fact that Dr. Bigg failed to correlate Patient E's area of concern with her mammographic images, he concluded in his screening mammogram MG report on this date that Patient E's mammogram was "[n]egative."

g. The targeted right ultrasound images obtained at this May 22, 2019 visit revealed a mass in Patient E's right breast at 6:00 5 cm FN, which in comparison to the patient's 2017 and 2018 ultrasound images, was growing. Yet, Dr. Bigg failed to note in his May 22, 2019 report that he was following this growing lump/mass for almost three consecutive years, and again failed to appropriately manage this increasing mass by recommending biopsy. Rather, Dr. Bigg opined in this report that patient E's ultrasound images demonstrated a *dermal cyst* on the right, despite the fact that there are no imaging features to support this impression. Again, Dr. Bigg erroneously concluded that Patient E's overall results were negative, giving her a BI-RADS (discussed in detail below) rating of 1, and recommended annual mammography in follow-up. Yet based on Patient E's diagnostic imaging at this time, her BI-RADS rating was a 5 (highly suspicious for breast cancer).

h. Less than one month later, on or about June 19, 2019, Patient E presented to her treating dermatologist on recommendation from Dr. Bigg, for consultation regarding a purported dermal cyst on her right breast. On physical examination, this dermatologist noted a large (approximately 2 cm), hard nodule on Patient E's right breast, in the same area of concern, noting that he could not rule out a cancerous nodule/mass. This dermatologist's treatment records indicate that on July 5, 2019, Patient E returned to his office for an excisional biopsy of this "rock hard mass," and his treatment note on this date indicates that once he made an incision in Patient E's right breast, there was no cyst sac and the tissue was necrotic, favoring malignancy. Post-biopsy pathology results indicated atypical glandular proliferation, consistent with breast carcinoma.

i. On or about July 18, 2019, Patient E presented to another practitioner who ordered a breast ultrasound. This ultrasound showed a bilobed mass of 2.45 cm; the larger lobe with a fluid pocket and the smaller lobe appearing solid, determined to be a malignant neoplasm (assuming this was the biopsied cancer from the dermatology office) in the lower inner right breast quadrant[8]; as well as a 6mm axillary lymph node. The following day, Patient E underwent a right lumpectomy for a 2.8 cm intracystic papillary carcinoma, and sentinel lobe biopsy.

j. Despite the fact that, beginning in or about June 15, 2016, Patient E reported a palpable lump in her right breast, none of Dr. Bigg's mammogram and/or ultrasound reports between June 2016 and May 2018 reference a palpable lump.

7. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the care and treatment of Patient F, a female patient with a personal history of follicular thyroid cancer and a family history of breast and lung cancer, from approximately May 22, 2018 (when the patient was 46 years old) to January 8, 2019. Specifically, Dr. Bigg and/or his

[8]This was determined to be a new, primary occurrence of breast cancer, not a recurrence of Patient E's previous breast cancer, which was located in the upper, outer quadrant of the breast.

employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient F for a new, palpable, solid left breast lump/mass, resulting in his failure to diagnose the patient's left breast cancer. Specifically:

a. On or about February 13, 2018, Patient F presented to Dr. Bigg with a new, palpable mass in her left breast, at which time she underwent bilateral mammogram and ultrasound. In his screening mammography, bilateral and ultrasound, bilateral report on this date, Dr. Bigg noted a 5mm diameter firm, mobile "nodule," which he palpated at "the site in question." Patient F's breast density precluded visualization of the palpable mass in the left breast mammographic images as obtained by ABC RTs and reviewed by Dr. Bigg. Yet, Dr. Bigg failed to note the absence of mammographic correlation of the mass in his report. Regarding Patient F's ultrasound images, Dr. Bigg noted that he thought these images "probably" showed the patient's "palpable [left] nodule" to be a fibroadenoma or fibroma, and further noted widespread calcifications throughout both of the patient's breasts. Rather than appropriately recommending additional diagnostic mammographic work up of a mass and calcifications, Dr. Bigg indicated that Patient F would be returning for short-term ultrasound follow-up to confirm the presence of the left breast "palpable nodule."

b. Prior to this short-term ultrasound follow-up, Dr. Bigg obtained and reviewed Patient F's June 27, 2017 mammogram. In his February 19, 2018 supplemental screening mammography report (signed the following day), Dr. Bigg purportedly compared Patient F's February 13, 2018 ABC mammogram with her June 27, 2017 mammogram. Again, despite the fact that he could not visualize Patient F's palpable left breast mass in the February 13, 2018 ABC mammographic images, Dr. Bigg nonetheless concluded that the patient's ABC (February 13, 2018) "screening" mammogram was benign,

and recommended yearly mammography in follow-up. Standard of care for a palpable mass requires additional imaging and/or biopsy.

c. Approximately three months later, on or about May 22, 2018, Patient F returned to ABC for short-term left breast ultrasound. In his breast ultrasound report on this date, Dr. Bigg opined that Patient F's ultrasound images showed continuing coarse calcification of "the small nodule that is the palpable mass on the left side close to the midline," again opining that this "nodule" was a fibroadenoma. At this time, it was evident from a comparison of Patient F's current ultrasound images to her ultrasound images from three months' prior (February 13, 2018), that the patient's palpable mass was growing. Yet, Dr. Bigg failed to recommend biopsy of this growing, palpable mass. Rather, he simply concluded that Patient F's screening was benign, and recommended that the patient return for her annual screening mammogram.

d. On or about January 8, 2019, Patient F returned to ABC for her annual screening mammogram and ultrasound. At this time, mammographic images showed segmental calcifications in Patient F's left breast at 9:00, and the patient's ultrasound images showed a 4.7 cm irregular mass in the left breast, as well as left breast masses at 8:00. In Dr. Bigg's January 8, 2019 screening mammogram MG report, he described his physical finding of an easily-palpated, enlarging, mobile, hard, lobular mass measuring about 3cm in diameter in Patient F's left breast, which he noted was "at the location of [a] previously identified small fibroadenoma." Again, as this mass was not visible in Patient F's mammographic images, there was no mammographic correlation of this physical finding. On reading Patient F's ultrasound images on this date, Dr. Bigg failed to identify and describe the cancerous findings noted above. Rather, Dr. Bigg offered an inaccurate description (not a diagnostic finding) of a single mass in Patient F's left breast, indicating in this report that Patient F's ultrasound revealed a solid, lobular, approximately 3 cm in diameter, non-shadowing mass with identifiable, amorphous calcifications within

the solid area, concluding at this time that the enlarging mass represented a substantial change from Patient F's earlier ultrasounds and clinical evaluation. After following the growing mass in Patient F's left breast for approximately eleven months, Dr. Bigg noted that biopsy should be considered.

e. The following day, on referral from another treating physician, Patient F presented to a surgeon for consultation regarding her left breast mass. This surgeon indicated in her Progress Note on this date that Patient F had a lump in her breast for "a while," which had "never been biopsied" at ABC, and had become painful. The surgeon's physical examination revealed a 3.5 cm mass in Patient F's left breast, at 9:00. Ultrasound-guided biopsy performed that day showed a 3.6 x 3.7 x 1.4 cm irregular, lobulated mass at 9:00 6 cm FN, with internal calcifications and septations. January 11, 2019 pathology results indicated invasive mammary (ductal) carcinoma. In or about June 2019, Patient F completed chemotherapy, followed by bilateral skin-sparing mastectomies with left axillary sentinel lymph node biopsy.

f. As detailed above, Patient F's breast density precluded visualization of the enlarging mass in the left breast mammographic images as obtained by ABC RTs and reviewed by Dr. Bigg. In that regard, Dr. Bigg failed to order and RTs employed by Dr. Bigg failed to produce sufficient, complete or appropriate mammographic and/or ultrasound imaging of Patient F's left breast from approximately February 13, 2018 through January 8, 2019, as follows:

i. On or about February 13, 2018 and January 8, 2019, Dr. Bigg failed to order a diagnostic mammogram for Patient F, who presented with palpable findings in her left breast. Rather, on each occasion Dr. Bigg ordered or authorized a screening mammogram, which is appropriate only for an asymptomatic patient.

ii. Patient F's February 13, 2018 and January 8, 2019 mammographic images did not include a triangle metal marker placed in the area of concern (location of palpable left breast mass)

designated by the patient, and thereby failed to appropriately focus attention on the area of the mass and its correlation on the mammograms.

iii. The ABC RTs failed, on or about February 13, 2018 and January 8, 2019, to obtain additional mammographic spot compression views of two orthogonal projections, in this area of patient concern.

iv. On or about February 13 and May 22, 2018, and January 8, 2019, Patient F's left breast ultrasound images were not labeled to appropriately designate the patient's area of concern.

8. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the care and treatment of Patient G, a female patient, from approximately July 24, 2019 (when she was 56 years old) to January 14, 2020. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient G for a palpable, enlarging, solid right breast lump/mass, resulting in the failure to diagnose the patient's right breast cancer, as follows:

a. Patient G's January 2, 2018, and January 11, 2019 mammographic and ultrasound images, obtained at ABC and reviewed and interpreted by Dr. Bigg, indicate the presence of an enlarging mass in Patient G's right breast. Yet, Dr. Bigg failed to document this mass in any of these corresponding imaging reports (which from comparison of Patient G's 2018, 2019 and 2020 mammographic images, discussed below, was enlarging).

b. On or about July 24, 2019, Patient G presented to Dr. Bigg complaining of a palpable mass in her right breast (present since in or about March 2019). In his Unilateral Diagnostic Mammogram MG report on that date, Dr. Bigg documented that he physically examined a mass in Patient G's right breast, which was present on mammogram and ultrasound, at this time acknowledging that this

mass "was present previously"(though previously undocumented, as detailed above)[9]. Dr. Bigg indicated his impression that this mass was a "small lymph node." He concluded that Patient G's mammogram was "benign," and he instructed Patient G to perform monthly breast examinations and return if she noticed a change; otherwise return for screening mammography.

c. On or about January 14, 2020, Patient G returned to ABC for a "screening" mammogram and ultrasound. Patient G's mammographic images showed a 3 cm mass in her right breast at 10:00, and targeted ultrasound images showed a 2.5 cm irregular mass at 10:00, indicating evident cancer. Appropriate management of evident cancer is biopsy. Yet, in his January 14, 2020 Screening Mammogram MG report, Dr. Bigg opined that the mammographic images showed "a minimally enlarging solid nodule laterally on the right side almost certainly representing an enlarged lymph node," despite the fact that there are no imaging signs of a lymph node in the 10 o'clock position. Dr. Bigg advised Patient G to return for yearly mammography. After this mass had grown for approximately three years on the mammogram images, Dr. Bigg arranged for a surgical consultation "because of the increase in size."

d. On or about that same day, Patient G presented to a surgeon, on referral from Dr. Bigg. This surgeon performed and/or reviewed a right breast ultrasound, showing a 2.5 cm hypoechoic irregular mass, taller than wide on some images, and performed a right breast biopsy, noting that "[r]egardless of pathology, will recommend excision of right breast mass, as typically do not leave enlarging breast masses in post-menopausal women." On or about January 16, 2020, Patient G's right breast core biopsy results showed invasive ductal carcinoma with mucinous features.

e. Dr. Bigg failed to order, and radiologic technologists ("RTs") employed by Dr. Bigg failed to produce, sufficient, complete or appropriate mammographic and ultrasound imaging of Patient G's right breast, as follows:

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[9]As Dr. Bigg failed to previously document Patient G's right breast mass, he likewise failed to document that this mass was growing, as shown in the patient's breast imaging dating from 2015, as detailed above.

i. On or about January 14, 2020, Dr. Bigg failed to order a diagnostic mammogram for Patient F, who presented with palpable findings in her right breast. Rather, Dr. Bigg ordered or authorized a screening mammogram, which is appropriate only for an asymptomatic patient.

ii. Mammographic images produced on or about July 24, 2019 and January 14, 2020 by the ABC RT(s) did not include triangle metal markers placed in the area of concern (location of palpable right breast lump/mass) designated by the patient, and thereby failed to appropriately focus attention on the areas of the lump/mass and its correlation on the mammogram.

iii. Despite the fact that Dr. Bigg noted Patient G's concern with a palpable lump/mass, which he documented, Dr. Bigg failed on these dates to order and review additional mammographic spot compression views of two orthogonal projections, in the area of patient concern.

iv. The ABC RT(s) failed to appropriately target Patient G's July 24, 2019 and January 14, 2020 diagnostic ultrasound images, in that the RT(s) did not label these images to designate the patient's area of concern.

v. Patient G's January 14, 2020 ultrasound images do not include images of the patient's right axilla; a single image labeled "axilla" is blank.

9. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the care and treatment of Patient H, a female patient, from approximately December 13, 2017 (when she was 71 years old) to May 14, 2019. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patient H for a palpable, enlarging, solid right breast lump/mass, resulting in his failure to diagnose the patient's right breast cancer, as follows:

a. On or about April 5, 2019, Patient H presented to Dr. Bigg complaining of pain and swelling around her right nipple, at which time she underwent unilateral right side mammography and ultrasound at ABC. A comparison of these current images to Patient H's December 13, 2017 and December 18, 2018 mammographic and ultrasound images indicated an increasing mass in the patient's right breast, requiring biopsy referral. Yet, Dr. Bigg failed to make this finding in his (April 5, 2019) Unilateral MG report, or to recommend biopsy as appropriate management. Rather, after noting an "unremarkable" physical examination, Dr. Bigg found that Patient H's mammographic images demonstrated "some stable diffuse skin thickening around the nipple," and that the patient's ultrasound images suggested edema in the subcutaneous tissues behind the nipple. Dr. Bigg diagnosed Patient H with a "suspect[ed]…infection," and prescribed a course of antibiotics, recommending "return in the near future for evaluation." Dr. Bigg failed to record the name or dosage of the prescribed antibiotic in his treatment record for Patient H.

b. Less than six weeks later, on or about May 14, 2019, Patient H returned to Dr. Bigg/ABC, complaining of severe pain, including pain around the nipple and axillary pain, despite having completed a second course of prescribed antibiotics (which prescription Dr. Bigg also failed to document in his treatment record). In his Unilateral Diagnostic Mammogram MG report on or about this date, Dr. Bigg noted on physical examination diffuse thickening without erythema around Patient H's right nipple, with more noticeable nipple inversion. Despite the fact that Patient H's right mammographic images on this date showed an irregular 4.2 cm mass at 10:00, and two visible, abnormal right axillary lymph nodes, and her right targeted ultrasound images showed a 2.7 cm subareolar mass at 12:00, evidencing cancer, Dr. Bigg failed to note these findings. Further, despite the fact that Patient H's mammographic images showed two visible, abnormal right axillary lymph modes and her ultrasound images showed multiple, enlarged right axillary lymph nodes, Dr. Bigg failed to address the mammographic lymph node findings,

and misinterpreted the ultrasound lymph node findings as normal. Based on his erroneous assessment of Patient H's breast images, Dr. Bigg referred the patient to a surgeon for further treatment of a purported chronic infection.

c. On or about this same date (May 14, 2019), Patient H presented to a surgeon, who noted the patient's referral from Dr. Bigg for evaluation of right breast pain, worsening nipple inversion, and a rash present since March 2019, which failed to respond to antibiotics and "water therapy." After evaluating ultrasound images, this surgeon performed a right breast mass biopsy and fine needle aspiration of Patient H's right axillary lymph nodes, noting concern "for breast cancer with LN [lymph node] involvement." Subsequently, Patient H was diagnosed with malignant neoplasm of the central portion of her right breast, secondary and unspecified malignant neoplasm of the axilla and upper limb lymph nodes, axillary lymphadenopathy, and atypical ductal hyperplasia of the left breast; and treated with neoadjuvant chemotherapy, after which this surgeon recommended modified radical mastectomy.

10. On or about January 15, 2020[10], Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the care and treatment of Patient I, a 39-year-old female patient. Specifically, Dr. Bigg and/or his employees, acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately work-up, diagnose, and manage Patient I for a painful, palpable, right breast lump/mass, as follows:

a. Dr. Bigg failed to order, and radiologic technologists ("RTs") employed by Dr. Bigg failed to produce, sufficient, complete or appropriate mammographic and ultrasound imaging of Patient I's right breast, as follows:

[10]See Allegation #17 with respect to the other events and allegations relating to January 15, 2020.

i. On or January 15, 2020, Dr. Bigg failed to order a diagnostic mammogram for Patient I, who presented with palpable findings in her right breast. Rather, Dr. Bigg ordered or authorized a screening mammogram, which is appropriate only for an asymptomatic patient.

ii. Mammographic images produced on this date by the ABC RT did not include triangle metal markers placed in the area of concern (location of palpable right breast lump/mass) designated by the patient, and thereby failed to appropriately focus attention on the areas of the lump/mass and its correlation on the mammogram.

iii. Despite the fact that Dr. Bigg noted Patient I's concern with a palpable right lump/mass, he failed to order and review additional mammographic spot compression views of two orthogonal projections, in the area of patient concern.

iv. Only a single ultrasound image of Patient I's right breast was submitted, and the ABC RT failed to appropriately target this ultrasound image, in that the RT did not label the ultrasound image to designate the patient's area of concern.

b. Dr. Bigg's January 15, 2020 (signed January 16, 2020) New Patient – Screening Mammogram MG report shows that Dr. Bigg failed to note any physical findings, and failed to correlate Patient I's palpable right breast mass with her mammographic or ultrasound imaging.

c. Based on this insufficient imaging obtained by ABC RTs and reviewed by Dr. Bigg, Dr. Bigg concluded that Patient I's mammogram results were negative. Further, he failed to note in his report any ultrasound findings and failed to rate the patient's ultrasound results.

11. In or about July 2019, Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (13), and (16) regarding his care and treatment of Patient E. Specifically, at or about this time, Patient E's breast cancer surgeon called Dr. Bigg at ABC on three separate occasions, each time leaving a voicemail

message indicating she wanted to discuss a (mutual) cancer patient (Patient E), and leaving her cell phone number. Dr. Bigg failed to contact this physician regarding Patient E.

12. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the diagnosis and treatment of Patients A - I between approximately May 2016 and January 2020, in that, contrary to sound medical judgment and acceptable standards of medical practice, he failed to follow the Breast Imaging Reporting and Data System (BI-RADS)[11] system structure in formulating his reports. Specifically, Dr. Bigg failed to use appropriate and acceptable BI-RADS terminology to indicate the correct purpose of the underlying imaging or the patients' breast composition, or to adequately and/or accurately state the mammogram and ultrasound findings; resulting in his failure to meet the standard of care. Further, Dr. Bigg's reported diagnostic impressions were not supported by his report findings and led to serious mismanagement of these patients. This failure to comply with BI-RADS standardized reporting and management contributed to Dr. Bigg's reporting errors and omissions and caused delayed diagnoses, as detailed above and shown below. Specifically:

a. Regarding Patient A, in his May 29, 2018 screening mammography, unilateral left side, and ultrasound, unilateral left side report, Dr. Bigg:

[11]BI-RADS (Breast Imaging Reporting and Data System) is a reporting system developed by radiologists for the American College of Radiology (ACR) to aid the interpreting physician and referring physician in patient management. "BI-RADS serves as a comprehensive guide providing standardized breast imaging terminology, report organization and assessment structure, as well as a classification [rating system] for" breast image results [*The American College of Radiology BI-RADS ATLAS and MQSA: Frequently Asked Questions*, (Updated 5/1/11), quantason.com/pdf/breast_cancer_screening/bi_rads/american_college_of_radiology_bi_rads_ATAS_and MQSA_2011.pdf]. First developed in 1993, BI-RADS was initially used for mammograms. BI-RADS has been periodically updated as technology has changed to include its use with breast ultrasound and breast MRI, and is currently in its fifth edition. BI-RADS provides for structured reporting so that findings are clearly stated using BI-RADS-approved terminology, aiding the interpreting physician in correctly assessing the imaging findings. Per the applicable BI-RADS reporting conventions, each breast finding is listed separately in the interpreting physician's report, relative to each set of diagnostic images (e.g., mammogram, ultrasound, MRI). From the BI-RADS finding(s)/conclusion(s), the physician is required to recommend appropriate management of the finding(s)/conclusion(s) in accordance BI-RADS management requirements and terminology.

i. Failed to state the correct indication for the mammogram and ultrasound examination of Patient A, in that he erroneously labeled his diagnostic report a "screening" mammography, and ultrasound, unilateral left side report, despite the fact that the term "screening" is reserved for imaging/a report for an asymptomatic patient; whereas Patient A presented with a palpable lump and Dr. Bigg noted in this report "two soft adjacent nodules" on physical examination, as detailed above.

ii. Failed to succinctly describe Patient A's overall breast composition (e.g., overall assessment of the volume of attenuating tissues in the breast)[12] using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d.[13] Rather, Dr. Bigg described Patient A's left breast as "show[ing] a parenchymal pattern consistent with the Wolfe P1 category[14]."

iii. Failed to include a clear description of any important ultrasound findings using the standardized BI-RADS reporting system and standardized medical terminology. Rather, in the "Findings" section of this report, Dr. Bigg reported his impression of Patient A's left breast ultrasound images.

iv. Failed to adequately describe, using standard medical terminology, the location of the palpable masses (e.g., purported lymph nodes) in Patient A's left breast, relative to both the mammographic and ultrasound images, using a consistent and reproducible system, such as clock-face location and distance from the nipple. Rather, Dr. Bigg noted that Patient A presented with two soft, adjacent nodules "above the nipple on the left side," as discussed above.

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[12]Per BI-RADS, overall assessment of the volume of attenuating breast tissues helps indicate the "relative possibility that a lesion could be obscured by normal tissue and that the sensitivity of examination thereby may be compromised by dense breast tissue" [*ACR BI-RADS Atlas*].

[13]BI-RADS breast composition categories include the following: a: the breasts are almost entirely fatty; b: there are scattered areas of fibroglandular density; c: the breasts are heterogeneously dense, which may obscure small masses; and d: the breasts are extremely dense; which lowers the sensitivity of the mammography [*ACR BI-RADS Atlas*].

[14]The first mammographic density pattern classifications were developed by Wolfe in or about 1976. BI-RADS, the current classification system, is a modification of the Wolfe system.

v. Failed to correctly categorize the chance of malignancy by assessing Patient A's diagnostic results (indicating a palpable finding) pursuant to the BI-RADS lexicon.[15] Rather, Dr. Bigg rated Patient A's mammogram under "HHS Sec. 900.12(c)(1)," relative to mammographic quality standards applicable to ACR accreditation of imaging facilities.[16] Further, Dr. Bigg rated Patient A's mammogram results as "1 – Negative mammogram," despite the fact that a palpable mass finding under the BI-RADS lexicon cannot be negative, and must be rated as BI-RADS 2, 3, 4, or 5. Approximately six days after this ABC mammogram and ultrasound, Patient A presented to another practitioner and underwent a mammogram, (as detailed above) which this practitioner rated as BI-RADS 4B, suspicious for breast cancer, requiring a biopsy.

vi. As Dr. Bigg failed to appropriately assess/categorize Patient A's mammogram, he therefore failed to recommend appropriate management/follow-up.[17] Rather, based on his "negative" finding, Dr. Bigg instructed the patient to continue performing monthly breast examinations, to return if she noticed "any change," and to return "at the appropriate time for her annual screening mammogram." Contrarily, the mammogram obtained six days later by another practitioner and rated at BI-RADS 4B, detailed above, indicated the need for biopsy.

vii. Dr. Bigg's discussion of Patient A's ultrasound images, which he explained during his December 18, 2019 interview with the Department of Health Professions' ("DHP") investigator, further indicates his failure to understand and apply the appropriate BI-RADS nomenclature.

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[15]BI-RADS rating categories are as follows: Category 0: Incomplete (Needs Additional Imaging Evaluation and/or Prior Mammograms for Comparison); Category 1: Negative; Category 2: Benign; Category 3: Probably Benign; Category 4: Suspicious (Optional subdivisions: Category 4A: Finding needing intervention with a low suspicion for malignancy; Category 4B: Lesions with an intermediate suspicion for malignancy; 4C: Findings of moderate concern, but not for classic malignancy); Category 5: Highly Suggestive of Malignancy; Category 6: Known Biopsy-Proven Malignancy.
[16]U.S. Code of Federal Regulations, Title 21, Chapter 1, § 900.12.
[17]BI-RADS follow-up recommendations for rating categories are as follows: Category 0: Recall for additional imaging; Category 1: Routine screening; Category 2: Routine screening; Category 3: Short-interval (6-month) follow-up or continued surveillance; Category 4: Tissue diagnosis (biopsy); Category 5: Tissue diagnosis (biopsy); Category 6: Surgical excision when clinically appropriate.

Specifically, while viewing Patient A's two May 28, 2019 ultrasound images with the DHP investigator, Dr. Bigg described "nice capsule, low density, solid nodes, no shadow, each has echogenic center, which is a characteristic of fat, and a surrounding fatty rind of lymphoid tissue," opining, "That's what lymph nodes look like." Yet, the requisite BI-RADs ultrasound descriptors for a solid mass do not include terms such as "nice capsule." Further, the term "low density" is a BI-RADS descriptor for the lightness or darkness of a finding viewed on mammogram, not on ultrasound, as this term is used to describe the greyscale of a mammogram.

b. Regarding Patient B, in his November 27, 2017 screening mammography, bilateral and ultrasound, bilateral report, Dr. Bigg:

i. Failed to succinctly describe Patient B's overall breast composition using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d. Rather, Dr. Bigg described Patient B's left breast as "show[ing] a parenchymal pattern consistent with the Wolfe N1 category."

ii. Indicated in the "Findings" section that ultrasound images showed prominent lymph nodes in the right axilla, the largest by ultrasound measuring 2 cm in long diameter, that had increased in size from the patient's last mammogram (November 17, 2016);[18] failing to adequately describe, per the BI-RADS lexicon, the physical characteristics of; or the specific location of the purported lymph nodes, relative to both the mammographic and ultrasound images, using a consistent and reproducible system, such as clock-face location and distance from the nipple.

[18]Dr. Bigg's November 17, 2016 screening mammography, bilateral and ultrasound, bilateral report indicated "unchanged" findings on the "left side," which he opined, "represent a little reactive change associated with an old silicone rupture…stable." These findings failed to indicate the size or location of the "reactive change," indicated "2 – Benign findings" and recommended yearly mammography in follow-up. Dr. Bigg's November 16, 2015 screening mammography, bilateral and ultrasound, bilateral report indicated findings of "A little soft tissue silicone on the "right side" unchanged from earlier examinations, indicated "2-Benign," and recommended yearly mammography in follow-up.

iii. Failed to rate Patient B's mammogram and ultrasound results according to the BI-RADS lexicon. Specifically, Dr. Bigg indicated, "HHS Sec. 900.12(c)(1)" as a "1- Negative mammogram." Appropriate application of the BI-RADS ratings to Patient B's results would have resulted in a rating of 2, 3, 4 or 5 (any rating other than BI-RADS 1, which is "negative").

iv. Based on his failure to appropriately rate Patient B's mammogram and ultrasound results, Dr. Bigg failed to appropriately manage the patient's right breast mass per the BI-RADS lexicon, which would require biopsy or surgical treatment.

c. Regarding Patient C, in his October 30, 2017 right breast ultrasound report, April 16, 2018 screening mammography, bilateral and ultrasound, bilateral report, and May 16, 2018 breast ultrasound report for Patient C, Dr. Bigg failed to:

i. Indicate in the report titles that the mammograms and/or ultrasounds were performed for diagnostic purposes, due to the presence of a mass in the patient's right breast.

ii. Succinctly describe Patient C's overall breast composition using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d.[19]

iii. Adequately describe the characteristics, size, and location of the purported fibroadenoma in Patient C's right breast, as well as the patient's area of concern, relative to the ultrasound images, using a consistent and reproducible system, such as clock-face location and distance from the nipple.

iv. Rate Patient C's diagnostic results (fibroadenoma) pursuant to the BI-RADS lexicon.[20] In each report, Dr. Bigg should have rated Patient C's imaging results as BI-RADS 3.

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[19]Dr. Bigg failed to include a breast tissue density description in his October 26, 2017 and May 16, 2018 imaging reports. In his April 16, 2018 screening mammography, bilateral and ultrasound, bilateral report, he described Patient C's breasts as "show[ing] a parenchymal pattern consistent with the Wolfe P2 category."

[20]Dr. Bigg failed to include this (any) rate on his October 30, 2017 and May 16, 2018 breast ultrasound reports. Dr. Bigg erroneously rated Patient C's April 16, 2018 screening mammography and ultrasound reports per an "HHS Sec 900.12(c)(1) Designation." There is no applicable BI-RADS category for abnormal, axillary lymph node(s).

v. Manage Patient C's diagnostic results pursuant to the BI-RADS lexicon. For each report, based on the appropriate BI-RADS rating of 3, Dr. Bigg should have recommended the appropriate, corresponding BI-RADS management of short interval follow-up or continued surveillance.

d. Regarding Patient D, in his May 16, 2017 and May 16, 2018 screening mammography, bilateral reports, Dr. Bigg failed to:

i. Indicate in the report titles that these mammograms were performed for diagnostic purposes, due to the presence of a palpable mass in the patient's left breast.

ii. Succinctly describe Patient D's overall breast composition using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d, as detailed above. Rather, Dr. Bigg indicated Patient D's "parenchymal pattern" was consistent with the "Wolfe P1 category."[21]

iii. Rate Patient D's diagnostic results pursuant to the BI-RADS lexicon, as detailed above. Rather, Dr. Bigg rated these results under "HHS Sec. 900.12(c)(1)" as a "1- Negative mammogram."

iv. Based on his failure to appropriately rate Patient D's mammogram and ultrasound results, Dr. Bigg failed to appropriately manage the patient's cancerous mass per the BI-RADS lexicon, which would require biopsy and/or surgical treatment.

e. Regarding Patient E, in his May 23, 2017 screening mammography, bilateral and ultrasound, bilateral report; January 9, 2018 diagnostic mammography, bilateral and ultrasound bilateral report; May 22, 2018 screening mammography, bilateral and ultrasound, bilateral report; and May 22, 2019 screening mammogram MR report, Dr. Bigg:

[21]Of note, in his July 9, 2012 – May 16, 2016 screening mammography, bilateral reports, Dr. Bigg categorized Patient D's parenchymal pattern as consistent with the Wolfe P2 category.

i. Erroneously labelled his May 23, 2017, May 22, 2018, and May 22, 2019 imaging reports, detailed above, as "screening" reports, despite the fact that Patient E complained of a palpable lump/mass in her right breast on or about each of these dates.

ii. Erroneously rated, in each of these reports, his mammographic findings. Specifically, as the area of concern (palpable mass) was not included on any of these mammographic images, Dr. Bigg should not have rated his findings. Yet, Dr. Bigg rated Patient E's May 23, 2017 mammogram as "HHS Sec 900.12(c)(1) Designation: 2 – Benign findings;" the patient's January 9 and May 22, 2018 mammograms "HHS Sec 900.12(c)(1) Designation: 1 – Negative mammogram;" and rated her May 22, 2019 as "BI-RADS 1 Negative Mammogram."

iii. Despite the fact that Patient E's ultrasound images showed a growing mass in the patient's right breast since May 23, 2017, Dr. Bigg failed to assign Patient E's January 9 and May 22, 2018 ultrasound images or her May 22 2019 targeted right ultrasound images (showing a mass in the patient's right breast at 6:00, 5 cm FN) a BI-RADS category, to indicate the level of suspicion for malignancy.

iv. Based on his failure to appropriately rate Patient E's mammogram and ultrasound results, Dr. Bigg failed to appropriately manage the patient's cancerous mass per the BI-RADS lexicon, which would require biopsy and/or surgical treatment.

f. Regarding Patient F's February 13, 2018 screening mammography, bilateral and ultrasound, bilateral report (subsequently amended per Dr. Bigg's February 19, 2018 screening mammography, supplemental report); May 22, 2018 breast ultrasound report; and January 8, 2019 screening mammogram MG reports, Dr. Bigg:

i. Failed to indicate in the report titles that these mammograms were performed for diagnostic purposes, due to the presence of a mass in the patient's left breast, as detailed above.

ii. Failed to succinctly describe Patient F's overall breast composition using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d, as detailed above. Rather, Dr. Bigg indicated in his February 13 and 19, 2018 and January 8, 2019 imaging reports for Patient F, that the patient's breasts showed a "parenchymal pattern" consistent with the "Wolfe DY" category. In his May 22, 2018 breast ultrasound report, Dr. Bigg failed to include a breast tissue density description.

iii. Failed to adequately describe the characteristics, size, and location of the purported fibroadenoma in Patient F's left breast, as well as the patient's area of concern, relative to the ultrasound images, using a consistent and reproducible system, such as clock-face location and distance from the nipple.

iv. Erroneously rated (non BI-RADS) Patient F's mammographic images in his February 13, 2108 and January 8, 2019 mammography reports, despite the fact that the patient's area of concern (palpable mass) is not seen on the mammogram images obtained by the ABC RTs and reviewed by Dr. Bigg on or about these dates, due to the patient's breast density.

v. Failed to rate Patient F's ultrasound imaging results pursuant to the BI-RADS lexicon, as detailed above. Rather, Dr. Bigg inaccurately noted "benign findings" regarding Patient F's February 13[22] (in this instance, pursuant to HHS Sec 900.12(c)(1)) and May 22, 2018 ultrasound images, despite the fact that comparison to previous imaging exams demonstrated that the mass in Patient

[22]Dr. Bigg subsequently included a February 19, 2018 supplemental screening mammography report in his chart for Patient F, indicating that in the interim from her last mammographic screening, he reviewed a June 27, 2017 mammogram for comparison. Dr. Bigg indicated at this time that the patient was scheduled to return for short-term ultrasound to confirm the presence of a fibroadenoma on the left side, calling for a "status change" to Designation: 2 - Benign findings, pursuant to HHS Sec 900.12(c)(1), and advised that Patient F return for a short-term breast ultrasound in follow-up, "to confirm the presence of a fibroadenoma on the left side."

F's left breast was increasing in size and showed suspicious imaging features. Further, Dr. Bigg failed to rate the (missed) finding of left breast masses at 8:00, evident in Patient F's January 8, 2019 ultrasound images.

vi. Based on his failure to appropriately rate Patient F's ultrasound results, Dr. Bigg failed to appropriately manage the patient's cancerous mass per the BI-RADS lexicon, which would require biopsy or surgical treatment.

g. Regarding Patient G's July 24, 2019 Unilateral Diagnostic Mammogram MG report and January 14, 2020 Screening Mammogram report, Dr. Bigg failed to:

i. Indicate in the title of these reports that the patient underwent ultrasound imaging.

ii. Indicate in the January 14, 2020 report title that the mammogram (and ultrasound) were performed for diagnostic purposes, due to the presence of a mass in the patient's right breast, as detailed above.

iii. Succinctly describe Patient G's overall breast composition using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d. Rather, Dr. Bigg described Patient G's left breast as "show[ing] a parenchymal pattern consistent with the Wolfe category P1" on each of these dates.

iv. Adequately describe the characteristics, size, and location of the purported mass/lymph node in Patient G's right breast, relative to the ultrasound images, using a consistent and reproducible system, such as clock-face location and distance from the nipple.

v. Based on his erroneous, repeat finding of an enlarged (enlarging) lymph node, erroneously rated Patient G's diagnostic results pursuant to the BI-RADS lexicon, as "BIRADS 2: Benign Findings," for which appropriate management is return to routine screening. (Inappropriately

noting that this BI-RADS determination was pursuant to HHS Sec. 900.12(C)(1)). Had Dr. Bigg appropriately interpreted Patient G's mammograms and ultrasound images, the appropriate BI-RADS rating for an enlarging and/or cancerous mass would have been 4, the appropriate management of which is biopsy.

h. Regarding Patient H's April 5, 2019 Unilateral Mammogram MG and May 14, 2019 Unilateral Diagnostic Mammogram MG reports, Dr. Bigg:

i. Failed to indicate in the title of his report that Patient H's April 5, 2019 mammogram was for diagnostic purposes, and failed to indicate in the titles of Patient H's April 5 and May 14, 2019 reports that the patient underwent ultrasound imagining on these dates.

ii. Failed to succinctly describe Patient H's overall breast composition in either report using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d. Rather, Dr. Bigg described Patient H's right breast as showing a parenchymal pattern consistent with "the Wolfe Category P1."

iii. Based on his erroneous, repeat finding of a chronic, right breast infection, erroneously rated Patient H's May 14, 2019 diagnostic results as "BIRADS 2: Benign Findings," for which appropriate management is return to routine screening (inappropriately noting that this BI-RADS determination was pursuant to HHS Sec. 900.12(C)(1)). Further, had Dr. Bigg appropriately interpreted Patient H's mammograms and ultrasound images on this date, the appropriate BI-RADS rating for a cancerous breast mass with lymph node involvement is 4, for which appropriate management requires breast mass and lymph node(s) biopsy. Instead, Dr. Bigg referred Patient H to a surgeon for assessment of non-specific changes and suspected infection.

i. Regarding Patient I's January 15, 2020 New Patient – Screening Mammogram MG report, Dr. Bigg:

i. Erroneously labeled this report a "Screening" mammogram, despite the fact that the patient presented with a palpable right breast lump, and failed to indicate in the report title that an ultrasound was performed.

ii. Failed to succinctly describe Patient H's overall breast composition in either report using the appropriate BI-RADS breast fibroglandular tissue density category of a, b, c or d. Rather, Dr. Bigg described Patient H's right breast as showing a parenchymal pattern consistent with "the Wolfe category P1."

iii. Failed to note any mammogram or ultrasound findings.

j. Regarding Patients A – I, Dr. Bigg failed to separately rate, per the BI-RADS lexicon, mammographic and ultrasound images. Rather, he rated only his mammographic image impressions or conclusions.

13. From approximately August 2017 through October 2019, Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations in the care and treatment of female Patients J – R. Specifically, Dr. Bigg and/or his employees acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to appropriately assess/work-up, diagnose, and manage Patients J - R, who presented to ABC for breast imaging during this period, resulting in Dr. Bigg's failure to diagnose breast cancer in these patients. Further, Dr. Bigg failed to meet appropriate standards of breast imaging radiology practice by following strict terminology in breast imaging reports as defined in the BIRADS lexicon and atlas (detailed above), and otherwise omitted and/or included erroneous information in these patients' imaging reports. Specifically:

a. Regarding Patient J, whom Dr. Bigg treated from approximately December 2017 (when she was 48 years old) through September 2018:

i. On or about December 14, 2017, Patient J presented to Dr. Bigg complaining of a new, palpable mass in her left breast, which Dr. Bigg described on physical examination as a "mobile, slightly tender left breast nodule." Despite Patient J's noted new breast symptomatology, ABC RTs performed and Dr. Bigg reviewed a screening mammogram, which is appropriate only for an asymptomatic patient, as detailed above.

ii. Dr. Bigg noted in his December 14, 2017 Screening Mammography Bilateral and Ultrasound Bilateral report that on this date Patient J's mammography revealed a "relatively high density smooth nodule" in the area of the patient's palpable mass. In using the descriptors "smooth nodule," Dr. Bigg failed to follow BI-RADS terminology requirements for describing a mammographic breast mass finding. Further, Dr. Bigg failed to include any of Patient J's December 14, 2017 mammography images, on which his report was based, in his treatment record for the patient.

iii. Patient J's December 14, 2017 breast ultrasound showed a hypoechoic mass with indistinct and angular margins; sonographic descriptors that are highly suspicious for carcinoma. Had he appreciated these suspicious features, under the BI-RADS lexicon, Dr. Bigg should have ordered a biopsy. However, Dr. Bigg's report shows that he incorrectly perceived this mass, on ultrasound, to represent an 11 mm diameter "cyst," which he concluded was "[b]enign." Per the BI-RADS lexicon, management of such a benign assessment is return to routine screening mammogram. Yet, Dr. Bigg recommended that Patient J return for short interval follow up to monitor the "benign" cyst.

iv. Three months later, on or about March 19, 2018, Patient J returned to ABC for a follow-up ultrasound, which again showed the highly suspicious mass in Patient J's left breast. At this time, Dr. Bigg erroneously concluded in his Breast Ultrasound Report that this mass was a "complex cyst." Patient J's March 19, 2018 ultrasound images showed an additional, similar-appearing, suspicious

mass at the 3:00 position of the patient's left breast. Yet, Dr. Bigg failed to appreciate, identify, or note this additional suspicious mass in his ultrasound report for Patient J.

v. Six months later, on or about September 18, 2018, Patient J returned to ABC with continued left breast complaints. Patient J's mammographic images on this date showed that the mass had continued to increase in size and now filled a large portion of the patient's left breast. Dr. Bigg's physical examination indicated associated features of diffuse hardness, breast retraction, marked swelling of the nipple, and skin thickening. Despite the diffusely abnormal appearance of Patient J's left breast on the ultrasound, as well as these physical indications, Dr. Bigg interpreted the patient's imaging studies as showing "simple mastitis," noting "no focal masses are appreciated." Contrary to Dr. Bigg's impression, these findings represent the continued growth of a breast cancer that should have been biopsied at the first appearance in 2017.

vi. Despite diagnosing Patient J with simple mastitis, on or about September 18, 2018, Dr. Bigg assessed the patient's imaging studies as BI-RADS 4, "Suspicious Findings," noting that biopsy should be considered. On or about that same date, Patient J presented to a surgeon who noted the patient's palpable left breast mass, nipple drainage and changes, and pain for the previous three weeks. At this time, Patient J underwent left breast core biopsy, which showed Grade 2 invasive ductal carcinoma.

vii. On or about September 24, 2018, Patient J's bilateral breast MRI showed a biopsy-proven malignant mass occupied the patient's entire left breast, with skin and nipple involvement, and also revealed an enlarged left axillary lymph node and an enlarged left internal mammary lymph node. Patient J's MRI report was assessed as BI-RADS 5: Highly Suspicious for Malignancy. September 27, 2018 pathology results indicated metastatic carcinoma in Patient J's left axillary lymph node.

viii. In or about October 2018, Patient J underwent neoadjuvant chemotherapy, and on or about March 26, 2019, the patient underwent left modified radical mastectomy and right prophylactic mastectomy.

b. Regarding Patient K, who had a family history of breast cancer and whom Dr. Bigg treated from approximately May 16, 2018 (when she was 41 years old) to May 16, 2019:

i. On or about May 16, 2018, Patient K presented to Dr. Bigg at ABC for a screening mammogram. Patient K's mammographic images on this date demonstrated a mass within the patient's inferior right breast, which Dr. Bigg failed to appreciate, identify or note in his May 16, 2018 Screening Mammography, Bilateral report. Consequently, Dr. Bigg failed to order and review additional mammographic and/or ultrasound views for further evaluation of this mass. Rather, Dr. Bigg erroneously noted that Patient K's mammogram was negative, pursuant to HHS Sec 900.12(c)(1) Designation: 1. Based on his inappropriate assessment, Dr. Bigg recommended that Patient K return for annual screening mammography.

ii. One year later, on or about May 16, 2019, Patient K returned to Dr. Bigg at ABC for her annual screening mammogram. Due to poor patient positioning by ABC RTs during imaging, this same mass was only partially visible in Patient K's right breast mammographic images on this date. However, the mass was still noticeable when compared side by side with the prior comparison study (May 16, 2018 ABC mammogram). Yet, despite specifically noting that he compared Patient K's 2018 and 2019 mammographic images, Dr. Bigg again failed to appreciate, identify or note this mass within the patient's inferior right breast. Consequently, Dr. Bigg maintained that Patient K's mammogram was negative (on this occasion BI-RADS 1), and recommended return to annual mammogram in follow-up.

iii. Less than three months later, on or about September 11, 2019, Patient K presented to another physician complaining of a palpable lump in her right breast, present for

approximately one month, as well as bilateral breast tenderness. This physician scheduled the patient for mammogram and ultrasound, which on or about September 19, 2019 showed:

- In mammographic images, an irregular, high density mass with a spiculated margin in the right breast at 7:00 posterior depth, highly suggestive of malignancy. In ultrasound images, a 1.3 cm x 1.2 cm x 1.1 cm irregular mass with spiculated margin @ 7:00 posterior depth 8 cm FN, correlating with mammography findings and Patient K's palpable area of concern.

- In mammographic images, an irregular, equal density mass with a spiculated margin in the right breast at 8:00 posterior depth, highly suggestive of malignancy. In ultrasound images, a 0.5 cm x 1.1 cm x 0.6 cm irregular mass with an indistinct margin at 8:00 posterior depth 8 cm FN.

- Fine, pleomorphic calcifications in a linear distribution in the right breast at 9:00 posterior depth. Highly suggestive of malignancy.

- In mammographic images, an enlarged node in the right axilla, suspicious of malignancy. In ultrasound images, an enlarged right axillary lymph node.

The treating radiologist assessed these images/Patient K's overall study as BI-RADS 5: Highly Suggestive of Malignancy, and on this same date performed ultrasound-guided biopsies, which indicated, concordant with the mammographic and ultrasound images detailed above:

- Malignant, invasive ductal carcinoma in the right breast at 7:00 posterior depth, Grade 2.

- Malignant, invasive ductal carcinoma in the right breast at 8:00 posterior depth, Grade 2.

- Malignant, metastatic disease to the right lymph node.

iv. In or about October 2019, Patient K began neoadjuvant chemotherapy. In or about December 2019, Patient K was planning bilateral mastectomy with immediate reconstruction followed by Herceptin for an additional six months, as well as radiation therapy, given her node-positive disease.

c. Regarding Patient L, whom Dr. Bigg treated from October 31, 2017 (when she was 64 years old) through September 12, 2019:

i. On or about October 31, 2107, Patient L presented to Dr. Bigg at ABC for bilateral screening mammography and ultrasound, and the patient's ultrasound images demonstrated a hypoechoic, anti-parallel, irregular mass in her left breast at the 4:00 position. These are all highly suspicious imaging features, categorized as a BI-RADS 5 mass (meaning greater than (>) 95% chance of malignancy), for which the corresponding management is biopsy. However, Dr. Bigg failed to appreciate, identify or note Patient L's left breast mass in his October 31, 2017 Screening Mammography, Bilateral, Ultrasound, Bilateral report for the patient, thereby erroneously concluding that Patient L's imaging studies were negative, pursuant to HHS Sec 900.12(c)(1) Designation 1. Based on this erroneous negative assessment, instead of ordering a biopsy, Dr. Bigg recommended that Patient L return to routine (annual) mammographic screening.

ii. On or about September 12, 2019, Patient L returned to ABC complaining of a palpable left breast mass. Comparison of Patient L's mammographic images showed that her current left breast mass had increased in size (from the patient's October 31, 2107 mammogram). Yet, Dr. Bigg reported this mass in his September 12, 2019 Screening Mammogram MG report as a "*new* lobular, high-density nodule on the left side," measuring over one centimeter (1 cm) in diameter. Dr. Bigg failed to further describe this mass within his report, regarding shape, orientation, or margins, or in terms of an appropriately-detailed location. Further, despite noting a "new" mass, Dr. Bigg failed to obtain additional (spot compression) mammographic and/or ultrasound views to adequately evaluate this purported new finding. Moreover, absent such additional imaging, Dr. Bigg erroneously interpreted Patient L's purported "new" left breast mass as a fibroadenoma, which is the most common benign solid mass radiologists see in the breast. However, fibroadenomas are round or oval in shape (not irregular) and have circumscribed

margins (not irregular). Moreover, post-menopausal women such as Patient L do not develop new or enlarging fibroadenomas. Further, despite the fact that a fibroadenoma is assessed as BI-RADS 1: Benign finding, Dr. Bigg assessed Patient L's imaging on this date as BI-RADS 4: Low Suspicion, yet indicated that biopsy should be performed.

iii. On or about September 17, 2019, Patient L presented to a surgeon for evaluation, at which time the surgeon palpated a mass in the lower, outer quadrant of Patient L's left breast at 4:00, 4 cm FN. Left breast ultrasound on that date showed a 19 x 18 mm hypoechoic mass equally tall as wide, with no posterior shadow and irregular borders, concerning for malignancy. September 30, 2019 biopsy results revealed that this mass was invasive ductal carcinoma. On or about November 6, 2019, Patient L underwent a left breast lumpectomy.

d. Regarding Patient M, whom Dr. Bigg treated from approximately August 30, 2017 (when she was 61 years old) through September 10, 2019:

i. Patient M's August 30, 2017 ABC mammographic images showed fine, pleomorphic calcifications (microcalcifications)[23] in the patient's right breast at 12:00, which Dr. Bigg failed to appreciate, identify, or note in his Screening Mammography, Bilateral, Ultrasound, Bilateral report on this date. Instead, Dr. Bigg concluded that no suspicious microcalcifications were seen. Consequently, instead of ordering and reviewing additional diagnostic mammographic and/or ultrasound views to further evaluate these microcalcifications, Dr. Bigg assessed Patient M's breast images on this

[23]Microcalcifications are small areas of calcium that appear on mammograms and are usually, but not exclusively, changes in the milk ducts or within stroma of the breast. They are common and most women have some. However, when they are new or increasing, standard of care requires that they be evaluated with magnification views. These views assist in evaluating the morphology, as this determines whether or not the microcalcifications need to be biopsied. Some microcalcifications are typically benign on those views and need no further testing, while the rest of new microcalcifications usually require biopsy as they can be the first signs of early breast cancer, typically ductal carcinoma in situ, which is a Stage 0 breast cancer. Regarding Patients M, N, P, and Q (addressed below), whose primary findings were microcalcifications, none were further evaluated with additional magnification views.

date as HHS Sec 900.12(c)(1) Designation: 1 – Negative, and recommended return to annual screening mammogram.

ii. A year later, on or about August 30, 2018, Patient M returned to Dr. Bigg at ABC for screening mammography, which on this date showed that the fine, pleomorphic calcifications in the patient's right breast had increased in extent, again requiring evaluation with additional diagnostic mammographic views and/or ultrasound. As Dr. Bigg again failed to appreciate, identify, or note these microcalcifications in his Screening Mammography, Bilateral, Ultrasound, Bilateral report on this date, he failed to obtain these additional mammographic or ultrasound views, and again assessed Patient M's breast images on this date as "BIRADS 1 - Negative Mammogram."

iii. Approximately a year later (on or about September 4, 2019), when Patient M returned to Dr. Bigg at ABC, screening mammographic images showed that the patient's right breast calcifications had significantly increased in size, in comparison to her 2017 and 2018 ABC mammographic images. Yet, Dr. Bigg reported the microcalcifications evident in Patient M's current mammographic images as a "new" finding. Further, Dr. Bigg failed to further evaluate the purported new microcalcifications with mammographic spot magnification and/or ultrasound views, in order to determine their morphology and distribution. In the absence of such requisite diagnostic views, Dr. Bigg assessed Patient M's screening mammogram as BIRADS 4 B: Moderate Suspicion, a final BI-RADS Assessment category that should never originate from a screening mammography report, and which is an audited metric in breast imaging. Dr. Bigg noted that biopsy should be considered.

iv. On or about September 10, 2019, Dr. Bigg reported performing a stereotactic biopsy of a "lesion" in Patient M's right breast, noting in his corresponding report that he would follow up with Patient M the next day to discuss the pathology results. Yet, Dr. Bigg's records for Patient M do not include documentation of a follow-up consultation regarding said results.

v. In or about September 2019, Patient M was diagnosed by another physician with high-grade right breast intraductal carcinoma in situ, and a September 19, 2019 bilateral breast MRI showed a linear, non-mass enhancement measuring 3.0 cm at 9:00, 2 cm FN in the right breast at the site of the biopsy-proven carcinoma. On or about October 7, 2019, Patient M underwent a right breast lumpectomy, followed by adjuvant radiation therapy.

e. Regarding Dr. Bigg's care and treatment of Patient N, from approximately August 21, 2018 (when she was 68 years old) through September 22, 2019:

i. On or about August 21, 2018, Patient N, with a family history of breast cancer, presented to Dr. Bigg at ABC for screening mammography, which demonstrated a mass at the junction of the middle and posterior one-third upper-outer quadrant of the patient's right breast. Dr. Bigg failed to appreciate, identify, or note this mass in his Screening Mammogram MG report on this date. Based on his failure to appreciate Patient N's right breast mass, Dr. Bigg erroneously assessed the patient's mammogram as BI-RADS 1: Negative, and recommended routine, annual screening mammography in follow-up.

ii. Approximately one year later, on or about August 28, 2019, Patient N returned to ABC, with dimpling over the upper-outer quadrant of her right breast. Despite this noted symptomatology, ABC RTs performed and Dr. Bigg reviewed, screening mammography for this patient. On this date, mammographic imaging for Patient N showed that the mass present on her August 2018 right breast imaging had increased in size, with new/increasing microcalcifications, and ultrasound images showed an approximately 3 cm mass. Yet, Dr. Bigg still failed to obtain additional diagnostic mammographic views of the mass or microcalcifications. In the absence of such additional diagnostic images, Dr. Bigg assessed Patient N's breast imaging as BI-RADS 4B: Moderate Suspicion. On or about September 11, 2019, rather than performing an ultrasound-guided biopsy of Patient N's underlying right

breast mass, Dr. Bigg performed a stereotactic biopsy of the patient's right breast microcalcifications (referred to as a "lesion" in his stereotactic biopsy report). Dr. Bigg noted in his report on this date that he would follow up with Patient N the next day to discuss the pathology results, yet his records for Patient N do not include documentation of a follow-up consultation regarding said results.

iii. Approximately 13 days later, on or about September 24, 2019, Patient N presented to a surgeon on referral from Dr. Bigg, for evaluation and consultation regarding a new right breast Grade 1 invasive lobular carcinoma, which this surgeon indicated was diagnosed by Dr. Bigg pursuant to the stereotactic biopsy detailed above. Patient N's October 4, 2019 bilateral breast MRI showed that this biopsy-proven malignancy "seem[ed] more extensive than suggested by the [ABC] mammogram measuring 4.2 x 5.7 x 1.3 cm, [and that the] anterior component curve[d] towards the nipple and extend[ed] for up to 3.2 cm." On or about November 11, 2019, Patient N underwent a right breast lumpectomy and right axillary sentinel lymph node biopsy, deep. The November 14, 2019 surgical pathology report for Patient N showed a 4 cm-diameter invasive lobular carcinoma with periductal and lymphatic extension, and metastatic carcinoma (0.8 cm) to one lymph node.

f. Regarding Patient O, with breast implants and a family history of breast cancer, whom Dr. Bigg treated from approximately August 29, 2018 (when she was 70 years old) to May 29, 2019:

i. On or about August 29, 2018, Patient O presented to Dr. Bigg at ABC for a screening mammogram, which demonstrated a new focal asymmetry within the posterior one-third lateral central portion of the patient's left breast. Dr. Bigg failed to appreciate, identify, or note this mass in his Screening Mammogram with Implants MG report on this date. Further, by report, a screening ultrasound was performed, although no images were saved from that study. Based on his misread/misinterpretation of Patient O's mammographic images (and potentially the patient's ultrasound images), Dr. Bigg

erroneously assessed these images as BI-RADS 1: Negative, and recommended that Patient O return for an annual screening mammogram.

ii. One year later, on or about August 29, 2019, Patient O returned to Dr. Bigg at ABC for a screening mammogram with ultrasound. Patient O's ultrasound images demonstrated an irregular hypoechoic mass in the patient's left breast at the 3:00 position, 10 cm FN. In his Screening Mammogram with Implants MG report on this date, Dr. Bigg described this mass as a "multicystic area without clear evidence of a discrete mass," which was palpable (as a hard area immediately lateral to the left nipple). Instead of appropriately issuing a final assessment of BI-RADS 4: Suspicious, and performing a biopsy, Dr. Bigg gave Patient O a final assessment category of BI-RADS 1: Negative, for which the appropriate BI-RADS follow-up is return to normal screening. Yet, Dr. Bigg referred Patient O for a surgical consultation "based on clinical and ultrasound appearance," failing to document why a "multicystic area" would be suspicious enough on "ultrasound appearance" to warrant surgical referral, yet warrant a final BI-RADS assessment of Negative instead of Suspicious.

iii. The next day (on or about August 30, 2019), Patient O presented to a surgeon on referral from Dr. Bigg. This surgeon ordered a breast biopsy, which indicated, on or about October 3, 2109, invasive lobular carcinoma of Patient O's left breast. On or about October 14, 2019, Patient O underwent left breast lumpectomy and left axillary lymph node biopsy, deep. Post-surgical pathology results revealed a Grade 2, 4.5 cm invasive lobular carcinoma (with 90% being invasive) with left breast sentinel lymph node involvement (with a 2.1 mm metastatic lobular carcinoma focus). Approximately two months later, on or about December 10, 2019, Patient O underwent total bilateral mastectomy with reconstruction. This surgeon advised Patient O that due to the size of the mass in the patient's left breast, radiation treatment was necessary.

g. Regarding Dr. Bigg's care and treatment of Patient P, with a personal history of pancreatic cancer (2013) and a family history of breast, cervical and uterine cancer (mother), whom Dr. Bigg treated from approximately September 18, 2017 (when she was 65 years old) through October 2, 2019:

i. On or about September 18, 2017, Patient P presented to Dr. Bigg at ABC for screening mammography, which demonstrated a mass within the patient's right breast, with associated microcalcifications. Appropriate treatment required further evaluation of the mass and microcalcifications with additional diagnostic mammographic and/or ultrasound views. However, Dr. Bigg failed to appreciate, identify or note these findings or order such additional imaging. Consequently, Dr. Bigg erroneously assessed Patient P's mammography as Negative (pursuant to HHS Sec 900.12(c)(1) Designation:1) and recommended return to yearly mammography in follow-up.

ii. One year later, on or about September 20, 2018, Patient P returned to Dr. Bigg at ABC for a screening mammogram, which demonstrated that the mass and microcalcifications in the patient's right breast had increased in size since her last mammogram (September 18, 2017). However, Dr. Bigg again failed to appreciate, identify or note these findings or order additional imaging such as additional diagnostic mammographic and/or ultrasound views. Consequently, Dr. Bigg erroneously assessed Patient P's mammography as BI-RADS 1: Negative, specifically noting, "No suspicious microcalcifications or masses are seen." Based on his erroneous assessment, Dr. Bigg recommended that Patient P return to yearly mammography in follow-up.

iii. On or about September 20, 2019, the patient underwent repeat screening mammography at ABC. On this date, two years after the aforesaid mass and microcalcifications were originally visible in Patient P's ABC mammography, Dr. Bigg identified what he described as "new" microcalcifications in the patient's right breast. Yet, despite noting this purported new finding, Dr. Bigg

failed to order, obtain or review additional diagnostic mammographic and/or ultrasound views of these microcalcifications in order to evaluate their morphology or distribution. Further, while ultrasound on this date demonstrated a 2.3 cm suspicious mass in Patient P's right breast, Dr. Bigg failed to mention or describe this ultrasound study and images in his September 20, 2019 Screening Mammogram MG report. It is evident that Dr. Bigg failed to appreciate Patient P's associated right breast mass, as on or about October 2, 2019, he performed a stereotactic biopsy of the patient's microcalcifications, but failed to perform an ultrasound-guided biopsy of the underlying mass. October 3, 2019 pathology results from Patient P's stereotactic biopsy (not included in Dr. Bigg's records for Patient P) showed invasive, intraductal carcinoma.

h. Regarding Patient Q, whom Dr. Bigg treated from approximately January 24, 2018 (when she was 72 years old) through October 15, 2019:

i. On or about January 24, 2018, Patient Q presented to Dr. Bigg at ABC for a mammogram, which showed fine, pleomorphic calcifications (microcalcifications) in the upper, outer quadrant of the patient's left breast. Yet, Dr. Bigg failed to order or review diagnostic mammographic and/or ultrasound views of and/or biopsy these calcifications at this time.

ii. On or about October 3, 2019, Patient Q returned to Dr. Bigg at ABC with a new breast complaint of nipple retraction. Dr. Bigg failed to order and review an ultrasound to evaluate the periareolar tissues, which would be the acceptable practice in the evaluation of nipple retraction Further, despite Patient Q's new breast symptomatology and current mammographic images which showed that the microcalcifications in the patient's left breast had increased in size from her January 24, 2018 mammogram, on this date ABC RTs performed and Dr. Bigg reviewed screening mammographic images. On noting a "suspicious area" of "ill-defined increased density laterally with associated microcalcifications," Dr. Bigg recommended biopsy.

iii. As Dr. Bigg did not order or perform an ultrasound-guided biopsy in an attempt to identify a potential mass, on or about October 15, 2019, Dr. Bigg performed a stereotactic guided core needle biopsy of Patient Q's left breast microcalcifications. Biopsy pathology results indicated ER+ (70%) left breast ductal carcinoma in situ, nuclear grade 2, with necrosis and microcalcifications, fibrocystic changes, and fibroadenoma.

i. Regarding Patient R, with a family history of breast cancer, whom Dr. Bigg treated from approximately October 23, 2018 (when she was 51 years old) through October 17, 2019:

i. Patient R's October 23, 2018 ABC screening mammography demonstrated a focal asymmetry with microcalcifications in the patient's left breast. Dr. Bigg failed to appreciate, identify or note this finding in his Screening Mammography MG report on this date. Consequently, rather than appropriately ordering and evaluating these new left breast microcalcifications with additional magnification and/or ultrasound views, Dr. Bigg erroneously concluded that Patient R's final mammogram assessment was BI-RADS 1: Negative, and recommended that the patient return for yearly mammogram in follow-up.

ii. Approximately one year later, on October 17, 2019, Patient R returned to Dr. Bigg at ABC. At this visit, Patient R complained of a palpable left breast mass, which Dr. Bigg confirmed by physical examination, also noting a palpable area of thickening adjacent to the patient's left nipple. Despite Patient R's new breast symptomatology, the ABC RT performed, and Dr. Bigg reviewed, a screening mammogram. Further, the ABC RT failed to appropriately mark Patient R's area of palpable concern. In his Screening Mammogram MG report on this date, Dr. Bigg identified Patient R's left breast microcalcifications; however, he failed to obtain and review additional diagnostic views to evaluate their distribution or morphology. Ultrasound on this date demonstrated an irregular hypoechoic mass with spiculated margins and internal echogenic foci, which correspond to the mammographic

microcalcifications. Yet Dr. Bigg failed to order or review imaging through the axilla to evaluate for lymphadenopathy. Further, Dr. Bigg erroneously described this left breast mass as "a relatively smooth...nodule," failing to follow the strict breast imaging report terminology as defined in the BIRADS lexicon and atlas.

iii. On or about October 25, 2019, Patient R presented to a surgeon on Dr. Bigg's recommendation. At this visit, Patient R underwent ultrasound and biopsy. This surgeon reported that Patient R's ultrasound showed a hypoechoic, irregular mass in the patient's left breast, measuring 1.3 cm with no posterior shadowing. On or about November 14, 2019 Patient R's biopsy results showed high-grade, invasive ductal carcinoma in situ with comedo necrosis.

j. Regarding Patients J, L, N, O and R, Dr. Bigg failed to order, and RTs employed by Dr. Bigg further failed to produce, sufficient, complete or appropriate mammographic and ultrasound imaging of the patients' breasts, as follows:

i. On various dates from approximately December 2017 to October 2019, when Patients J, L, N O, and R presented to Dr. Bigg at ABC with areas of palpable concern, mammographic images produced by ABC RTs did not include triangle metal markers placed in these designated areas, thereby failing to appropriately focus attention on the areas of palpable concern and their correlation on the mammogram(s). Specifically, ABC RTs failed to place said markers:

- On or about December 14, 2017 when Patient J complained of a new, palpable left breast mass.
- On or about or about September 12, 2019, when Patient L complained of a new, palpable left breast mass.
- On or about August 28, 2019, when Patient N presented with dimpling over the upper-outer quadrant of her right breast.
- On or about August 29, 2019 when Dr. Bigg palpated a "hard area" immediately lateral to Patient O's left nipple.
- On or about October 17, 2019, when Patient R complained of a palpable left breast mass (with a palpable are of thickening adjacent to the patient's left nipple).

ii. On various dates from approximately December 14, 2017 to October 17, 2019, when Patients J, O, and R presented to Dr. Bigg at ABC with areas of palpable concern, ABC RTs failed to appropriately target these areas by labelling the ultrasound images to designate these areas of concern. Specifically, ABC RTs failed to appropriately label ultrasound images:

- On or about December 14, 2107, when Patient J presented complaining of a new, palpable left breast mass, and on or about March 19, 2018, when Patient J presented for a follow-up ultrasound regarding this mass.
- On or about August 29, 2019, when Dr. Bigg palpated a "hard area" immediately lateral to Patient O's left nipple.
- On or about October 17, 2019, when Patient R complained of a palpable left breast mass (with a palpable are of thickening adjacent to the patient's left nipple).

k. Regarding Patients J - R, Dr. Bigg failed to use appropriate BI-RADS mass descriptors within his imaging reports regarding the shape, orientation, or margins of said masses, and further failed to adequately describe the location of any noted findings, as detailed above. As Dr. Bigg failed to appropriately report the morphological features of the patients' mammographic and/or ultrasound findings, he failed to determine the appropriate BI-RADS final assessment categories and include these categories in every breast imaging report. Consequently, Dr. Bigg failed to recommend the appropriate, corresponding BI-RADS management for these patients. This failure to comply with BI-RADs standardized reporting and management caused delayed diagnoses, as detailed above.

14. Dr. Bigg violated Virginia Code§ 54.1-2915(A)(3), (12), (13), (16), and (18) and 18 VAC 85-20-26(C) of the Regulations regarding his care and treatment of Patients A – R, from approximately November 2015 to January 2020, in that he failed to follow the appropriate standard of care in treating, diagnosing and managing these breast cancer patients, as follows:

a. Regarding Patients A – I, despite the fact that Dr. Bigg differentiated patient mammogram reports by labelling them as "diagnostic" vs. "screening," as detailed above, there was no distinction in the underlying mammographic images on which each such report was based (e.g. the same

four mammographic views were obtained by the RTs whether the patient underwent a "screening" or a purported "diagnostic" mammogram).

b. Dr. Bigg's failure to accurately read/interpret Patient A – H's and Patient J - R's mammograms and ultrasounds, as well as his inclusion of erroneous and inaccurate information in the corresponding imaging reports for these patients, as detailed above, resulted in delayed breast cancer diagnosis for each of these patients. Delayed diagnosis thereby increases the chances of distant metastasis, increasing mortality, the need for more extensive surgery (mastectomy rather than breast conserving lumpectomy), and the need for chemotherapy (which may not be indicated for small breast cancers that are node negative).

15. Dr. Bigg violated Virginia Code § 54.1-2915(A)(3), (12), (13), (16) and (18) and 18 VAC 85-20-29(A)(1) of the Regulations, in that he delegated patient care to RTs employed by ABC who were not properly trained and supervised. Specifically:

a. By his own admission to the DHP investigator during his January 21, 2020 interview, Dr. Bigg does not train or require his RTs to appropriately place markers on mammographic images or label ultrasound images in instances of palpable patient findings, in violation of the applicable standards of care, as detailed above. Further, Dr. Bigg stated that the use of said markers is "old school" and "more the exception than the rule" in most practices. The ABC RTs currently performing mammographic and/or ultrasound imaging -- Individual 1 (employed full-time since approximately December 2017/January 2018), Individual 2 (employed full time since approximately August 2019), and Individual 3 (employed full time for approximately the past five years) -- affirmed Dr. Bigg's statement as such during their January 2020 interviews with the DHP investigator.

b. Despite the fact that neither Individual 1 nor Individual 2 is a certified ultrasound technologist, Dr. Bigg directed, authorized and/or allowed Individual 1 to perform ultrasounds "when

necessary," and directed, authorized and/or allowed Individual 2 to perform ultrasounds on patients with dense breast tissue or a family history of cancer, or who present with lumps.

c. Since approximately January 2015, ABC RTs performing mammography failed to adequately and appropriately position patients' breasts during mammographic imaging. Specifically:

i. Individual 4 stated that, during the course of her prior employment, ABC RTs were instructed by Dr. Bigg[24] and/or Individual 6 (a female relative of Dr. Bigg's, who is not a licensed health practitioner in any jurisdiction in the United States), to use minimal compression when performing mammograms, which Individual 4 opined, per her training and experience, was not enough compression to meet the standard of care in obtaining images of sufficient quality. Individual 4 further stated that Individual 6 would "fuss at" the RTs if a patient complained the mammogram was uncomfortable. Moreover, Individual 6 would visit the back waiting room several times daily to discuss with patients how much more comfortable mammograms were at ABC than at any other facility.

ii. Individual 3 stated that Dr. Bigg instructed the ABC RTs that patients' "breasts [don't] need to be flattened like pancakes."

iii. In or about August 2019, ABC failed to pass the ACR Mammography Quality and Standards Act ("MQSA") facility inspection/accreditation process, as required by applicable FDA regulations. Specifically, at least two images submitted by ABC at or about this time for this accreditation process were deemed insufficient, as patients' breasts were not sufficiently compressed in this imaging. Consequently, all of the ABC RTs (Individuals 1, 2 and 3) were required to complete a one-day imaging course focusing on mammography positioning. Purportedly, after the technologists completed this course and submitted new images, ABC was MQSA-accredited.

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[24]Dr. Bigg informed the DHP investigator during his January 21, 2020 interview that he is not certified or licensed to perform mammograms.

d. Despite the fact the instructor for the mammography course referenced above instructed Individuals 1, 2, and 3 that patients need to hold their breath to prevent motion during mammographic imaging, Individual 3 stated that Dr. Bigg never informed the technologists that patients should hold their breath. Individual 3 stated that since completing the course, she still does not ask patients to hold their breath, as in her opinion, most patients will release their breath while images are being taken, resulting in more motion.

16. Dr. Bigg violated Virginia Code § 54.1-2915(A)(1), (3), (12), (13), (16) and (18) and 18 VAC 85-20-30(E) of the Regulations, in that information posted and maintained on the ABC website is false, misleading or deceptive. Specifically, ABC's website (at www.allisonbreastcenter.com/index.html) states that:

a. Its "very latest Philips Microdose SI Mammogram machine" is "[m]ore comfortable than competitors. You do not even have to hold your breath," despite the fact that the mammography instructor associated with ABC accreditation efforts as detailed above, instructed ABC RTs to require patients to hold their breath during mammographic imaging.

b. ABC offers the "Highest resolution images worldwide," indicating that images obtained at ABC are of superior quality, despite the fact that, on multiple occasions, mammographic and/or ultrasound images obtained by ABC RTs and interpreted by Dr. Bigg for Patients A-R were of poor quality and/or insufficient to visualize the patients' areas of concern, as detailed above.

17. On or about January 15, 2020, Dr. Bigg violated Code § 54.1-2915(A)(3), (13) and (16) in that he treated patients while impaired, after purportedly ingesting three dosages of amitriptyline (a tricyclic antidepressant, C-VI), prescribed for Individual 6. Specifically:

a. Dr. Bigg stated, in his January 2020 interviews with the DHP investigator, that on or about the morning of January 15, 2020, he took three pills out of a "travelling pot" containing combined

medications for Individual 6 and himself, thinking that these pills were Advil. Dr. Bigg explained that he intended to take Advil for discomfort caused by a face cream prescribed by his treating dermatologist, but instead ingested three dosages of amitriptyline.

b. In a January 2020 telephone call with the DHP investigator, Dr. Bigg stated that after he ingested the three amitriptyline dosages, this medication "really did its job on my central nervous system," adding that after ABC staff noticed he was "getting wobbly," Individual 6 picked him up at ABC and drove him to a nearby hospital emergency department for evaluation and/or treatment.

c. During their January 2020 interviews with the DHP investigator, Dr. Bigg's staff reported the following occurrences on the morning of January 15, 2020:

i. Individual 3 stated that:

- At approximately 9:30 a.m., by which time she had seen/imaged approximately three patients, she went to put a patient chart in the imaging slots outside of Dr. Bigg's office when she noticed he was asleep in his chair. Individual 3 reported her observation to the ABC office manager, who instructed Dr. Bigg to "throw some water on his face." On speaking with Dr. Bigg, Individual 3 noted that his speech was slurred, and she opined he was having a stroke. Shortly thereafter, Individual 3 returned to the chart repository outside of Dr. Bigg's office and noted he again appeared to be asleep. Individual 3 and the office manager awakened Dr. Bigg, and the office manager called Individual 6. Prior to Individual 6's arrival, Dr. Bigg left his office to see another RT's (Individual 2's) patient, mumbling and running into the doorjamb when he exited his office.

- At approximately 10:30 a.m., Individual 3 asked Dr. Bigg to meet with a patient who presented with a huge lump, to review the patient's mammogram and ultrasound images; as Individual 3 did not see anything on the images, despite the known presence of the lump. Individual 3 observed that when he was speaking with patient, Dr. Bigg was mumbling, and his speech was difficult to understand.

- Subsequently, after Individual 6 arrived at the office to transport Dr. Bigg to the ED, Dr. Bigg stated that he had accidently ingested three dosages of Individual 6's pills, which she takes for a cough.

ii. Individual 1 stated that:

- She walked past Dr. Bigg's office at ABC at approximately 9:30 a.m., and noticed that he was slumped in his chair and appeared to be asleep. She alerted the office manager, and proceeded to see a patient. Individual 1 overheard the office manager telling Dr. Bigg to splash water on his face.

- Individual 2, who directly interacted with Dr. Bigg that morning, described Dr. Bigg's demeanor, to Individual 1, as "disoriented."

iii. Individual 2 stated that:

- Several days prior to January 15, 2020, Dr. Bigg appeared lethargic while at ABC. When Individual 2 asked how he was feeling, Dr. Bigg informed her that the dermatologic cream he applied to this face made him tired.

- On the morning of January 15, 2020, Individual 2 walked past Dr. Bigg's office and found him dozing in his chair, whereupon she awakened him. A short while later, she went to get Dr. Bigg to accompany her to the ultrasound room to consult with a patient, and found him asleep again. When Dr. Bigg awoke, he walked down the hallway to the ultrasound room, twice "smack[ing]" into the wall on the way. Individual 2 stated that Dr. Bigg was slurring his words and that she thought he had a stroke. Subsequently, Dr. Bigg examined the patient, who presented that morning with a breast lump. Individual 2 was not present when he later consulted with the patient in his office.

d. Dr. Bigg's January 15, 2020 hospital ED record indicates that he presented at approximately 11:34 a.m. complaining of dizziness, abnormal speech, numbness and balance problems. The attending physician's primary impression was hyponatremia, based on Dr. Bigg's laboratory bloodwork, for which she recommended admitting Dr. Bigg for treatment. The attending physician's secondary impression was of accidental drug ingestion (amitriptyline, per Dr. Bigg's self-report) and dysarthria. Dr. Bigg refused admission and was discharged later that day.

e. The following day when Dr. Bigg returned to ABC, Individual 1 requested that Dr. Bigg review all of the images taken the previous morning, and she reviewed the accompanying reports dictated by Dr. Bigg. Pursuant to her review, Individual 1 informed Dr. Bigg that he failed to note in two of these reports that the patients had undergone ultrasound imaging. Dr. Bigg corrected his patient reports accordingly.

18. Dr. Bigg violated Virginia Code § § 54.1-2915(A)(12) and (18), and 54.1-111(A)(7), and 18 VAC 85-20-105 of the Regulations, in that he willfully failed to respond to the DHP investigator's repeated investigation requests for a written response to questions and allegations, regarding his care and treatment of multiple patients, as follows:

a. Regarding Patients C, D, E and F, Dr. Bigg failed to respond to the following requests:

- A September 24, 2019 letter mailed to Dr. Bigg at ABC.
- October 30 and 31, 2019 telephone messages left for Dr. Bigg with ABC staff.
- A November 1, 2019 in-person request to and message left with ABC staff.
- A November 4, 2019 request sent to Dr. Bigg's personal e-mail address.
- A November 6, 2019 letter addressed to Dr. Bigg and hand-delivered to ABC.

b. Regarding Patients B, H, and J – R, Dr. Bigg failed to respond to the following requests:

- A December 2, 2019 letter hand-delivered to Dr. Bigg at ABC.
- A December 16, 2019 in-person request to Dr. Bigg at the ABC facility.

Of note, Dr. Bigg failed to provide the DHP investigator with a cell phone or alternate phone number for contact purposes.

19. Dr. Bigg is in violation of Virginia Code § 54.1-2915(A)(4) and (13), regarding the care and treatment of multiple patients at ABC, in that he conducts his ABC practice in such a manner as to endanger the health and welfare of his patients and the public. Specifically:

a. Regarding the high daily patient volume at ABC, directed by Dr. Bigg:

i. Dr. Bigg informed the DHP investigator during his December 18, 2019 interview that approximately 50 patients per day undergo diagnostic imaging at ABC. As a sole

practitioner, seeing this number of patients over the course of an eight-hour day allows Dr. Bigg less than ten minutes to complete each case (for diagnostic patients with multiple imaging studies such as mammogram and ultrasound); to include reading the patient's mammogram and ultrasound, performing a physical examination, discussing the results with the patient, and reporting on the patient's case.

ii. Similarly, RTs currently and previously employed by ABC stated during interviews with the DHP investigator in January 2020, as follows:

- Individual 1stated that approximately 49-70 patients were seen daily at ABC.

- Individual 3 stated that during the past several years, after moving to a new, more expensive office with more expensive equipment, Dr. Bigg and Individual 6, the ABC CEO and current practice manager, informed the RTs that they must "get the revenue up," instructing them to see more patients. Individual 3 opined, "they are pushing us to our limits," and stated that approximately 40 – 60 patients are currently seen daily at ABC.

- Individual 4, formerly employed at ABC as a radiologic technologist from approximately January – March 2019, stated that during her employment, the practice was "extremely overbooked;" that mammography rooms were constantly triple-booked, with the technologists seeing approximately three patients every 15 minutes; and that the practice was working like a "factory."

- Individual 5, previously employed at ABC from approximately January 2014 – June 2019, reported seeing, during that period, approximately 50 patients per day while working full time.

Treating this number of patients daily at ABC greatly increases the risk of inaccuracy in interpreting diagnostic imagery, thereby compromising accurate and effective patient care.

b. Regarding hygiene and sanitation practices at ABC:

i. Dr. Bigg and Individual 6 recently travelled to the United Kingdom ("UK"), departing the United States on or about February 29, 2020, and returning on or about March 16, 2020, during the current COVID-19 pandemic. The following day (March 17, 2020), Dr. Bigg and Individual 6 returned to ABC – Dr. Bigg treating patients and Individual 6 interacting with patients in her role as

office manager. On or about March 24, 2020, Individual 1 stated, in her interview with the DHP investigator, that since her return, Individual 6 was wearing a mask sporadically while at ABC. On or about March 26, 2020, Individual 2 informed the DHP investigator that Individual 6 was out of the office with a bad cough, according to Dr. Bigg. On or about March 31, 2020, Individual 2 informed the DHP investigator that Individual 6 remained at home, and that Dr. Bigg stated, "She just can't shake the cough," asking staff whether anyone at home was sick.

ii. In March 2020 interviews and communications, Individuals 1 and 2 reported to the DHP investigator an office shortage of the following: face masks, hand sanitizer, exam gloves, and sanitizing wipes (i.e., for equipment). Individuals 1 and 2 stated that when Dr. Bigg and Individual 6 returned from their trip to the UK, detailed above, an order was placed for these items. Individual 1 stated she did not know when/if these supplies would arrive at the office. In the interim, Individual 1 and/or Individual 2 stated that:

- Dr. Bigg was not wearing gloves in the office (and had not done so prior to the current pandemic).
- Individual 6 instructed them, in order to conserve exam gloves, to wear the same pair of gloves (marked "single use") all day, washing the gloves with soap and water between patients.
- Individual 6 brought homemade sanitizer to the practice, consisting of a mixture of vodka, perfume, and moisturizer, of which Dr. Bigg approved.
- Dr. Bigg was wearing the same face mask for a week or longer, and instructed the RTs to do the same. Staff was not instructed regarding cleaning or storage of the masks while not in use.
- Dr. Bigg informed the RTs that in order to conserve sanitizing wipes, they should use one side of a wipe to clean the mammogram machine after one patient, save the wipe, and then flip the wipe over to clean the mammogram machine after the next patient. Individual 2 further stated that Dr. Bigg instructed her to use baby wipes if ABC ran out of sanitizing wipes.

c. Dr. Bigg is incompetent to practice medicine and surgery with safety to patients and the public, in that he, including by and through his employees acting under his direction and control at ABC, failed, contrary to sound medical judgment and acceptable standards of medical practice, to

appropriately work-up, diagnose, and manage multiple ABC patients, failed to maintain complete and accurate records for these patients, and failed to conduct himself and his practice in a safe and responsible manner, as detailed above in Paragraphs 2 – 18 above.

See Confidential Attachment for the names of the patients and individuals referenced above.

for William L. Harp, M.D.
Executive Director
Virginia Board of Medicine

5/20/20
Date